United States District Court
For the Northern District of California

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4   UNITED STATES DISTRICT COURT

5   NORTHERN DISTRICT OF CALIFORNIA

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7   ORACLE CORPORATION, ET AL.,   Case No. 11-00910 JCS

8   Plaintiffs,

9   v.   **CLAIM CONSTRUCTION ORDER**

10 DRUGLOGIC, INC.,

11   Defendant
                                          /
12

13 DRUGLOGIC, INC.,

14   Counterclaimant,

15   v.

16 ORACLE CORPORATION, ET AL.,

17   Counterclaim-Defendants.
                                          /
18

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20 **I.   INTRODUCTION**

21   Plaintiffs Oracle Corporation and Oracle International Corporation ("Oracle") filed this

22 action against Defendant DrugLogic, Inc. ("DrugLogic") alleging infringement by DrugLogic of

23 Oracle's U.S. Patent No. 6,684,221 ("the '221 patent") and seeking a declaratory judgment of non-

24 infringement and invalidity as to DrugLogic's U.S. Patent No. 6,789,091 ("the '091 patent").

25 DrugLogic, in turn, brings a counterclaim alleging that Oracle is infringing the '091 patent. The

26 parties submitted ten claim terms for construction, consistent with Patent Local Rule 4-3 and the

27 Court's Case Management and Pretrial Order [Docket No. 55]. A tutorial was conducted on July 11,

28

2012 and a claim construction hearing was held the following day, on July 12, 2012. The Court's

final constructions are set forth below.[1]

II.   THE PATENTS-IN-SUIT

The patents-in-suit relate to the field of pharmacovigilence, which is the collection and

analysis of data regarding the risks of adverse effects from the use of a particular drug.

A.   The '091 patent

The '091 patent is entitled "Method and System for Web-Based Analysis of Drug Adverse

Effects." The named inventor is Victor Gogolak.   The application for the '091 patent was filed on

May 2, 2001. As originally drafted, claims 1 and 8 of the '091 patent read as follows:

> 1. A computer-implemented method for assessing and analyzing the risks of adverse effects resulting from the use of at least one [drug/substance][2] of interest, comprising:
>
> storing data regarding the risks of adverse effects from the use of at least one [drug/substance] of interest in one or more servers linked to the Internet;
>
> updating such data regarding the risks with additional information pertinent to the risks of adverse effects from the use of the at least one [drug/substance] of interest;
>
> permitting at least one remote user to access such data through the World Wide Web upon proper authentication;
>
> permitting the at least one user to identify the at least one [drug/substance] of interest;
>
> permitting the at least one remote user to select data stored in the one or more servers relevant to the safety of using the at least one [drug/substance] of interest;
>
> permitting the at least one remote user to analyze safety issues resulting from the use of the at least one [drug/substance] of interest; and
>
> permitting the at least one remote user to display such data and analysis.

Declaration of Christina Von Der Ahe in Support of Oracle's Brief Regarding the Construction of

the Disputed Terms in the '091 Patent ("Von Der Ahe Decl."), Ex. I ('091 Application). In an

Office Action dated June 18, 2003, the Patent and Trademark Office ("PTO") rejected all of the

original claims in the application over prior art. Von Der Ahe Decl., Ex. J (Office Action).   In

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[1]The parties have consented to the jurisdiction of the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

[2]Claim 1 uses "drug" throughout whereas claim 8 uses "substance" throughout.

response, the inventor added to the end of original claims 1 and 8 the following clause (hereinafter,

"the Wherein Clause"):

> wherein the step of permitting the at least one remote user to analyze comprises associating respective hyperlinks with a plurality of portions of such data and analysis, the plurality of hyperlinks respectively corresponding to places in an up and down hierarchy and allowing analytical drill down by selectively selecting successive hyperlinks, a last one of the hyperlinks in the up and down hierarchy linking to a previously-stored case describing adverse effects resulting from the use of the at least one drug of interest.

Von Der Ahe Decl., Ex. K at 3-4, 6 (March 4, 2004 Amendment). With that amendment, the claims

were allowed and the '091 patent issued on September 7, 2004.

B.   The '221 patent

The '221 patent is entitled "Uniform Hierarchical Information Classification and Mapping

System." The inventor, Kim Rejndrup, who was an Oracle employee, applied for the patent on May

8, 2000. The original application included 63 claims, including original claim 1, which stated as

follows:

> A method of storing clinical terms comprising defining a plurality of clinical terms; storing the clinical terms in a memory; and defining a plurality of relations corresponding to the plurality of clinical terms, the relations indicative of an association from a clinical term to at least one other of the plurality of clinical terms.

Declaration of Christina Von Der Ahe in Support of Oracle's Reply Brief Regarding the

Construction of Disputed Terms in the '221 patent ("Von Der Ahe Reply Decl."), Ex. A ('221 patent

Prosecution History) at 16.

On August 21, 2002, the PTO rejected claim 1 as obvious "over Coulter et al. (U.S. Patent

No. 5,201,048), Nakajima et al. (U.S. Patent No. 5,181,163), and Sasmor et al. (U.S. Pat. No.

4,825,968)." *Id*., Ex. B (Office Action dated August 21, 2002) at 2-3. The PTO found that: (1) the

Coulter reference taught defining terms and storing terms in a memory; (2) the Nakajima reference

taught defining relations and the association of relations; (3) the Sasmor reference taught the use of

clinical terms; and (4) it would have been obvious to one of ordinary skill in the art to combine these

references. *Id.*

3

1   Oracle's response to the rejection was received by the PTO on December 2, 2002. *Id*., Ex. F

2   (Amendment A to application, dated December 2, 2002). Oracle argued that it would not have been

3   obvious to combine Coulter, Nakajima, and Sasmor because they occupy different fields and

4   amended its claims to reflect the aspect of the invention it argued was non-obvious, the storing of

5   clinical terms in a memory "according to a hierarchy of relations." *Id*. at 6-7. For example, Oracle

6   amended claim 1 to add the underlined phrase:

7   A method of storing clinical terms comprising defining a plurality of clinical terms; storing
     the clinical terms in a memory <u>according to a hierarchy of relations</u>; and defining a plurality
8   of relations corresponding to the plurality of clinical terms, the relations indicative of an
     association from a clinical term to at least one other of the plurality of clinical terms.
9

10   *Id.* at i (underlined in Oracle's response to PTO rejection).

11   On February 7, 2003, the PTO again rejected all the claims of the patent. *Id*., Ex. G (Office

12   Action dated February 7, 2003). The Examiner found that claim 1 was obvious over Coulter,

13   Nakajima, Sasmor and Gusak (U.S. Patent No. 6,112,209). *Id.* In particular, the Examiner found

14   that although neither Coulter, Najakima nor Sasmor taught storing clinical terms "according to a

15   hierarchy of relations," such storage was taught by Gusak. *Id*. at 2-3.

16   On June 13, 2003, the applicant again amended the claims, amending claim 1 as follows:

17   A method of storing <u>a thesaurus of</u> clinical terms comprising defining a plurality of clinical
     terms <u>for use in conjunction with a clinical study</u>; storing the <u>plurality</u> clinical terms in a
18   memory according to a hierarchy of relations; and defining a plurality of relations
     corresponding to the clinical terms, the relations indicative of an association from a clinical
19   term to at least one other of the plurality of clinical terms.

20   *Id*., Ex. I at i (underlined in Oracle's response to PTO rejection). Oracle explained that the

21   amendments were intended to "specify, with more particularity, that the invention relates to a

22   thesaurus of clinical terms for use in conjunction with a clinical study." *Id*. at 6. Oracle argued that

23   "none of the cited [prior art] references relate to clinical studies" and none of those references

24   "address the issues associated with clinical studies, such as the inconsistencies in terminology in the

25   medical field." *Id*. at 8. On October 17, 2003, the PTO allowed the claims as amended. *Id*., Ex. J

26   (Notice of Allowability).

27   The Abstract of the '221 patent describes the invention as follows:

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A system and method to access and update a thesaurus of clinical terms employed in conjunction with a clinical study can be used to classify and map the clinical terms to related terms. A study term extracted from raw clinical data is presented to determine a corresponding match in the thesaurus of clinical terms. A table of relations is maintained to associate each clinical term with one or more related clinical terms in the thesaurus. A clinical term is mapped to one or more derived terms as indicated by the relations. The derived terms are processed to select a preferred term from the derived terms. An omission manager is operable to find a near matching candidate term if the clinical term is not found in the thesaurus. A plurality of different clinical terms can therefore be classified as corresponding to a common clinical term as indicated by the relations.

'221 patent, Abstract.

Two of the three disputed claim terms are found in claim 1, which states as follows:

> 1.   A method of storing a thesaurus of **clinical terms**
> comprising:
>
> > **defining a plurality of clinical terms for use in conjunction
> > with a clinical study**;
>
> > storing the plurality of clinical terms in a memory according
> > to a hierarchy of relations; and
>
> > defining a plurality of relations corresponding to the clinical
> > terms, the relations indicative of an association from
> > a clinical term to at least one other of the plurality of
> > clinical terms.

'221 patent, claim 1 (disputed claim terms in bold). The third disputed claim term is found in claim

12, a dependent claim which depends from dependent claim 2. Claim 2 recites the following:

> 2.   The method of claim 1, further comprising:
>
> storing the relations in the memory;
>
> providing a match term;
>
> querying the memory to find an occurrence of the match
> > term;
>
> traversing the relations corresponding to the match term;
> > and
>
> accumulating at least one derived term from the relations corresponding to the match term.

'221 patent, claim 2. Claim 12 states as follows:

> 12.   The method of claim 2 wherein providing a match
> term further comprises:
>
> > scanning **verbatim clinical data**; and

1   parsing verbatim study terms from the clinical data,
        wherein the verbatim study terms include the match
2   terms.

3   '221 patent, claim 12.

4   The claims of the '221 patent were allowed, as amended, on November 17, 2003.   Von Der

5   Ahe Reply Decl., Ex. J.

6   **III.   CLAIM CONSTRUCTION STANDARDS**

7   "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to

8   which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312

9   (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d

10   1111, 1115 (Fed. Cir. 2004)). Generally, claim terms are given the ordinary and customary meaning

11   that would be ascribed to them by a person of ordinary skill in the field of the invention. *Id*. at 1313;

12   *see also Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001)("[U]nless compelled

13   to do otherwise, a court will give a claim term the full range of its ordinary meaning as understood

14   by an artisan of ordinary skill").

15   The most "significant source of the legally operative meaning of disputed claim language" is

16   the intrinsic evidence of record, that is, the claims, the specification and the prosecution history.

17   *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). This is because "the

18   person of ordinary skill in the art is deemed to read the claim term not only in the context of the

19   particular claim in which the disputed term appears, but in the context of the entire patent, including

20   the specification." *Phillips*, 415 F.3d at 1312. In some cases, the specification may reveal a "special

21   definition" given by the inventor that differs from the meaning the term might otherwise possess. *Id*.

22   at 1316. In such instances, "the inventor's lexicography governs." *Id*. Similarly, a specification

23   may reveal "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id*.

24   A person of ordinary skill in the art also looks to the prosecution history of a patent to

25   understand how the patent applicant and the PTO understood the claim terms. *Id*. at 1313, 1317.

26   Under the doctrine of prosecution disclaimer, arguments and amendments made during patent

27   prosecution limit the interpretation of claim terms to exclude interpretations that were disclaimed to

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1 obtain allowance of a claim. *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576

2 (Fed. Cir. 1995). However, there is a heavy presumption that terms carry their full ordinary and

3 customary meaning unless the patentee "unequivocally imparted a novel meaning to those terms or

4 expressly relinquished claim scope during prosecution." *Omega Engineering, Inc, v. Raytek Corp*.,

5 334 F.3d 1314, 1323 (Fed. Cir. 2003) (citation omitted). Therefore, the Federal Circuit has declined

6 to apply the doctrine of prosecution disclaimer "where the alleged disavowal of claim scope is

7 ambiguous." *Id*. at 1324.

8   While claims are to be construed in light of the specification, courts must be careful not to

9 read limitations from the specification into the claim. *Phillips*, 415 F.3d at 1323. Thus, for example,

10 if a patent specification describes only a single embodiment of a claimed invention, that does not

11 mean the claims of the patent necessarily must be construed as limited to that embodiment. *Id*.

12 Rather, it is understood that the purpose of the specification "is to teach and enable those of skill in

13 the art to make and use the invention" and that sometimes, the best way to do that is to provide an

14 example. *Id*.

15   Courts may also use extrinsic evidence in construing claim terms if it is necessary, so long as

16 such evidence is not used to "vary or contradict the terms of the claims." *Markman v Westview*

17 *Instruments, Inc.,* 52 F.3d 967, 980 (Fed. Cir. 1995). As the court explained in *Markman*,

18 "[extrinsic] evidence may be helpful to explain scientific principles, the meaning of technical terms,

19 and terms of art that appear in the patent and prosecution history." *Id*. The Federal Circuit has

20 warned, however, that such evidence is generally "less reliable than the patent and its prosecution

21 history." *Phillips*, 415 F.3d at 1318. Thus, courts are free to consult dictionaries and technical

22 treatises so long as they are careful not to elevate them "to such prominence that it focuses the

23 inquiry on the abstract meaning of the words rather than on the meaning of the claim terms within

24 the context of the patent." *Id*. at 1321-22.

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1   **IV.   CONSTRUCTION OF CLAIM TERMS**

2   **A.   The '091 Claim Terms**

3   **1.   Claim Terms in the Wherein Clause of Claims 1 and 8**

4   **a.   "allowing analytical drill down"**

5   **i.   The Parties' Positions**

6

Druglogic's Proposed Construction	Oracle's Proposed Construction
"allowing the user to further analyze data by accessing more detailed, narrow, or granular information"	"allowing a user to redo the analysis in real time at different levels of the hierarchy"

9   Druglogic contends that the term "allowing analytical drill down" means "allowing the user

10   to further analyze data by accessing more detailed, narrow, or granular information." Druglogic

11   Inc.'s Opening Claim Construction Brief on United States Patent No. 6,789,091 ("Druglogic's

12   Opening Brief ('091 patent)") at 18. In support of its proposed construction, Druglogic cites two

13   passages in the specification that use the words "drill down," col. 9, ll. 10-28 and col. 9, l. 66 - col.

14   10, l. 5. *Id.* The first passage states as follows:

15   Preferably, if the user is reviewing a previously submitted correlation task at the
     Correlated Terms Line Listing Box 105, the present invention permits the user to access the
16   case list at the Case List Box 106, and further, permits the user to drill down on the
     individual elements in the case list and obtain case details in the Case Details Box 107.
17

18   Preferably, if the user is querying the system with regard to a drug at Drug Selector
     Page Box 111, then the present invention permits the user to access the drug profile at the
19   Profile Page Box 112, further, permits the user to access the case list at the Case List Box
     113, and still further, permits the user to drill down on individual elements in the case list
20   and obtain case details at the Case Details Box 114.

21   '091 patent, col. 9, ll. 10-28. The second passage states:

22   The output from the data mining engines is then preferably displayed in a Viewer 205, which
     can present the data in a variety of formats, including, but not limited to a sortable table, a
23   sortable line listing, and a radar screen, thus allowing rapid identification of signals and
     providing the user the ability to drill down to individual case details.
24

25   '091 patent, col. 9, l. 66 - col. 10, l. 5.

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1   Druglogic also cites to extrinsic evidence in support of its proposed construction. *Id.* at 19.

2 First, it cites to a definition of "drill down" from a Free On-Line Dictionary of Computing, or

3 "FOLDOC," which defines that term as follows:

4   **drill down**

5   <u>*<database>*</u> (Or "drill-down analysis") To examine data in greater detail, especially, in
       <u>reporting</u>, to interactively select some item from a summary and display the data that
6   contributed to that item, broken down by some extra parameter.

7   For example, when viewing your company's total worldwide sales for each month of this
       year, you might drill down to see October's sales by country, then again to see October's
8   sales in Afghanistan by product and so on.

9   This kind of analysis is often supported by some kind of <u>data warehouse</u>.

10 *Id*., Ex. 8.[3]

11   Second, Druglogic cites to a 2012 Wikipedia definition of "drill down," which states as

12 follows:

13   In information technology, to drill down means to move from summary information to
        detailed data by focusing in on something. In a [graphical user interface]-environment,
14   'drilling-down' may involve clicking on some representation in order to reveal more detail.

15   To drill down through a series of folders, for example, on a desktop means to move through
        the hierarchy of folders (from the top downwards) to find a specific file or to click through
16   drop-down menus in a [graphical user interface]. Clicking on an item moves you to a level of
        greater detail….
17
        Drilling down through a database involves accessing information by starting with a general
18   category and moving through the hierarchy: from category to file/table to record to field.
        When one drills down, one performs de facto data analysis on a parent attribute. Drilling
19   down provides a method of exploring multidimensional data by moving from one level of
        detail to the next. Drill-down levels depend on the data granularity.
20
21 *Id*., Ex. 10 (excerpt from Wikipedia, http://en.wikipedia.org/wiki/Drill_down, (2012)).

22   Third, Druglogic cites to the glossary in an Oracle user's manual which defines "drilldown"

23 as "[t]he process of uncovering more detailed information about the cases that are included in data

24 mining run results, in a case series, or in a report." *Id*., Ex. 4.

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27   [3]DrugLogic attached its extrinsic evidence as exhibits to its brief without providing a declaration
    authenticating the documents. DrugLogic did not provide a web address or publication date for the
28 FOLDOC definition.

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1   Finally, Druglogic argues that its proposed construction makes sense in light of "the entire

2   language" of claims 1 and 8. *Id*. In particular, the words "places in an up and down hierarchy"

3   refers to subsets of information "which are more or less specific relative to one another." *Id*. Thus,

4   DrugLogic asserts, "analytical drill down" is "simply the act of clicking through the hyperlinks

5   within the hierarchy to obtain more detailed information." *Id*. Similarly, the words following the

6   phrase "allowing analytical drill down," that is, "by selectively selecting successive hyperlinks, a

7   last one of the hyperlinks in the up and down hierarchy linking to a previously stored case . . ." refer

8   to the process of drilling down on successive hyperlinks within the hierarchy, lending further

9   support to DrugLogic's proposed construction, it contends. *Id*. at 20.

10   Oracle rejects DrugLogic's proposed construction, which it characterizes as "generic," on the

11   grounds that: 1) at the time of the invention, the term "allowing analytical drill down" did not have

12   an ordinary meaning; and 2) the patentee provided its own definition of the term in the specification.

13   Oracle's Brief Regarding the Construction of Disputed Terms in the '091 patent ("Oracle

14   Responsive Brief ('091 patent)") at 7. In support of the first point, Oracle cites to the declaration of

15   Stephen Jolley, an expert in drug safety auditing and compliance, who states that "[i]n May 2001,

16   when the '091 Patent was filed, the term 'analytical drill down' did not have a commonly-

17   understood meaning to one of ordinary skill in the fields of drug safety and pharmacovigilance." *Id*.

18   (citing Declaration of Stephen Jolley in Support of Oracle's Brief Regarding the Construction of

19   Disputed terms in the '091 Patent ("Jolley Decl."), ¶ 18).

20   Mr. Jolley further states that "[a]s one of ordinary skill in the art in May 2011 . . . [he] would

21   have understood 'analytical drill down' to mean that which it is defined to mean in Column 23, lines

22   41-51 of the '091 patent." Jolley Decl., ¶ 19. That section of the specification recites as follows:

23   The invention also allows "analytical drill down." That is, the ability to redo the analysis, in
      a preferred case, for a drug and a reaction system-organ-class. The user then selects the level
24   (e.g., PT) for-re-analysis and is given the results in real time. The user can then iterate
      between high level and detail. It will be appreciated that the invention is not restricted to
25   drug and reaction dimensions for proportional analysis. All pairs of the dimensions of the
      analytical engine (for example, reaction and outcomes) can be analyzed. Even within the
26   cases of a single drug, the reactions and concomitant drugs could be proportionally analyzed.

27   '091 patent, col. 23, ll. 41-51. According to Oracle, in this passage the patentee acted as his own

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1 lexicographer, setting off the term "analytical drill down" in quotation marks and using the words

2 "that is" to signal that a special definition is being provided. Oracle Responsive Brief ('091 Patent)

3 at 8 (citing *Sinorgchem Co., Shandong v. Int's Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir.

4 2007)). Accordingly, Oracle contends that the term "allowing analytical drill down" means

5 "allowing a user to redo the analysis in real time at different levels of the hierarchy." Oracle

6 contends that its proposed construction tracks the definition of "analytical drill down" in the passage

7 of the specification quoted above by making clear that the term means allowing a user to: "1) 'redo

8 the analysis' 2) at a selected 'level' and 3) receive the results 'in real time.'" *Id*.

9   The word "hierarchy" is not used in the definition provided in the specification but it is

10 referred to, Oracle asserts. *Id*. In particular, according to Oracle's expert, the references to "system-

11 organ-class" and "PT" in that definition "refer to different levels of the MedDRA hierarchy." Jolley

12 Decl., ¶ 20. Mr. Jolley explains:

13   MedDRA, the Medical Dictionary for Regulatory Activities, is a standardized medical
          dictionary that stores and classifies terms according to a five-level hierarchy. The five levels
14   of the hierarchy are System, Organ, Class (SOC); High Level Group Terms (HLGT); High
          Level Terms (HLT); Preferred Terms (PT), and Lower Level Terms (LLT).

15

16 *Id*. In other words, Oracle asserts, "[w]hen the '091 patent defines 'analytical drill down' as

17 allowing a user to do an analysis on the 'system-organ-class' level and then on the 'PT' (Preferred

18 Terms) level, to 'select[] the level' and to 'iterate between high level and detail', . . . the patent is

19 describing the ability to perform the analytical drill down of the '091 patent at different levels of the

20 *the MedDRA hierarchy*." Oracle Responsive Brief ('091 patent) at 9 (emphasis in original).

21   Oracle contends that DrugLogic's proposed construction is incorrect because DrugLogic

22 ignores the definition of the term that is provided in the specification (quoted above) "and attempts

23 to construe the term 'analytical drill down' as no different from the phrase 'drill down.'" *Id*. at 9-10.

24 According to Oracle, the term "analytical drill down" is different from "drill down." *Id*. at 10. This

25 is apparent, Oracle asserts, from the fact that the passages in the specification cited by DrugLogic,

26 which address "drill-down," *see* '091 patent, col. 9, ll. 10-28 and col. 9, l. 66 - col. 10, l. 5, are

27 followed – more than 10 columns later – by the statement that "[t]he invention *also allows*

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1   'analytical drill down.'" *Id*. at 10 (quoting '091 patent, col. 23, l. 41). Oracle argues that this shows

2   that the '091 patent "defines 'analytical drill down' as a different – and more specific – concept from

3   'drill down.'" *Id*.

4   Oracle rejects DrugLogic's reliance on a Wikipedia definition of "drill down," arguing that

5   that definition is irrelevant because it defines "drill down" rather than "analytical drill down" and is

6   from 2012 rather than the time of the invention. *Id*. It also cites cases in which courts have noted

7   that Wikepedia is "a particularly unreliable extrinsic source for purposes of claim construction." *Id*

8   (citing *Neev v. Abbott Med. Optics, Inc*., 2012 U.S. Dist. LEXIS 42024, at *34 (D. Del. March 26,

9   2012); *F5 Networks Inc. v. A10 Networks, Inc.*, 2011 U.S. Dist. LEXIS 89515, at *8 (W.D. Wash.

10 Aug. 11, 2011)).

11   Finally, Oracle disagrees with DrugLogic's contention that its proposed construction "makes

12 sense in context with the entire language" of claims 1 and 8. *Id*. (quoting DrugLogic's Opening

13 Brief ('091 patent) at 19). According to Oracle, this argument amounts to construing the term

14 "analytical drill down" to fit better with DrugLogic's "other arguments about what [c]laims 1 and 8

15 mean." *Id*. Instead, Oracle contends, the Court should take as its starting point the term that is

16 actually defined in the specification ("analytical drill down") and then construe the other disputed

17 terms in claims 1 and 8 in a manner that is consistent with that definition. *Id*. at 11.

18   In its reply brief, DrugLogic does not respond to Oracle's arguments relating to the extrinsic

19 evidence cited in its opening brief, implicitly conceding that this evidence does not provide strong

20 support for its proposed construction. Instead, DrugLogic focuses on the specification and claims of

21 the '091 patent, arguing that Oracle's position is flawed because: "1) it ignores the surrounding,

22 unambiguous language of the claims, 2) it imports limitations from a preferred embodiment, 3) it

23 misinterprets the specification's discussion of the term, and 4) it disregards language in the

24 specification that consistently describes 'drill down' as permitting the user to move from the

25 statistical analysis to a case list to case details." DrugLogic, Inc.'s Reply Brief on Claim

26 Construction of United States Patent No. 6,789,091 ("DrugLogic's Reply Brief ('091 patent)") at 10.

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1   As to the first point, DrugLogic contends that the language of the "Wherein Clause" makes

2 clear that the invention "merely *allows* analytical drill down and does not itself perform analysis

3 during drill down," *id*. at 11 (emphasis in original), and therefore, that the language in the

4 specification on which Oracle relies, that is, col. 23, ll. 41-51, "read in proper context" means that

5 "the invention *permits the user to analyze by giving the user 'the ability to redo the analysis'* [*i.e.*,

6 conduct the user's own analysis]." *Id*. (emphasis in original). According to DrugLogic, Oracle's

7 proposed construction "attempts to read out the unambiguous claim language that the invention

8 permits *the user* to analyze by allowing analytical drill down." *Id*. (emphasis in original).

9   DrugLogic argues that its proposed construction is also consistent with the references to

10 "drill down" throughout the specification and that Oracle's attempt to distinguish "drill down" from

11 "analytical drill down" has no basis. *Id*. DrugLogic points out that even if the term "analytical drill

12 down" may have had no established meaning in 2001, Oracle's expert conceded at his deposition

13 that the terms "drill down" and "analytical" had established meanings. *Id*. (citing Ex. A (Jolley Dep.

14 Excerpt) at 31-33). In particular, Mr. Jolley testified that "drill down would have been understood to

15 mean "going from higher level information to more detailed information." *Id*. (citing Ex. A at 31).

16 He agreed that "analytical," standing on its own, would have been understood to mean "of or

17 relating to analysis or analytics, especially separating something into component parts or constituent

18 elements." *Id*. (citing Ex. A at 32). According to DrugLogic, "[s]eparating the statistical analysis

19 into its component parts (*i.e.*, the case details underlying the analysis) is precisely what DrugLogic's

20 construction provides and the '091 patent describes." *Id*. at 12.

21   DrugLogic rejects Oracle's contention that the words "that is" at column 24, line 40 of the

22 '091 patent indicate that the language that follows is a definition of "analytical drill-down." *Id*. at

23 13. According to DrugLogic, because the specification uses the words "that is" rather than "is," this

24 section of the specification merely describes a preferred embodiment. *Id*. This conclusion finds

25 further support, according to DrugLogic, in the fact that the words "that is" are followed by the

26 words "in a preferred case." *Id*. "It is axiomatic," DrugLogic asserts, "that preferred embodiments

27 are not permitted to be read into claims, particularly where, as is the case here, the entirety of the

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1   patent suggests otherwise." *Id.* (citing *Comark Communs., Inc. v. Harris Corp.,* 156 F.3d 1182,

2   1187 (Fed. Cir. 1998)). DrugLogic further contends that the passage of the specification cited by

3   Oracle simply describes "a capability of the drill down step (*i.e.,* what the user can do with the

4   information once he or she drills down) and does not denote exclusion or restriction." *Id*. In this

5   regard, DrugLogic points to the testimony of Mr. Jolley, who testified that the words "in a preferred

6   case" mean "ideally" and are not mandatory. *Id*. n. 23.

7   Finally, with respect to Oracle's proposed inclusion of real time analysis at different levels of

8   the hierarchy, these limitations are inappropriate, DrugLogic contends, because the sentence in the

9   specification from which they are drawn states that the user can "then" select the level in the

10   hierarchy for reanalysis. *Id*. at 14 (citing '091 patent, col. 23, ll. 43-45). According to DrugLogic,

11   this indicates that this is merely a "subsequent step that can be performed as part of a preferred

12   embodiment." *Id*.

13   **ii.   Analysis**

14   The Federal Circuit has "repeatedly encouraged claim drafters who choose to act as their

15   own lexicographers to clearly define terms used in the claims in the specification." *Sinorgchem Co.,*

16   *Shandong v. International Trade Com'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). Thus, in *Phillips v.*

17   *AWH Corp.*, the Federal Circuit confirmed that "the specification may reveal a special definition

18   given to a claim term by the patentee that differs from the meaning it would otherwise possess" and

19   that "[i]n such cases, the inventor's lexicography governs." *Id*. (quoting *Phillips v. AWH Corp.*, 415

20   F.3d 1303, 1316 (Fed.Cir.2005) (en banc)). While the question of whether language in a

21   specification constitutes a definition turns on a number of factors, the Court finds that the language

22   found in col. 23, lines 41-51 of the '091 patent reflects a clear intent on the part of the patentee to

23   provide a special definition of the term "analytical drill down" and that Oracle's proposed

24   construction accurately reflects that definition.

25   In reaching its conclusion, the Court relies on several factors. First, the Court finds that the

26   language and punctuation of this passage are definitional. The fact that the words "analytical drill

27   down" are set off by quotation marks is a "strong indication that what follows is a definition." *See*

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1 *Sinorgchem Co., Shandong v. International Trade Com'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007)

2 (holding that language in specification defined a claim term based, in part, on the fact that term was

3 set off by quotation marks and noting that this is "often a strong indication that what follows is a

4 definition"). Similarly, the use of the words "that is" indicate that the inventor was giving the term

5 "analytical drill down" a special meaning. *Trading Technologies Intern., Inc. v. eSpeed, Inc.*, 595

6 F.3d 1340, 1353 (Fed. Cir. 2010) (holding that "the inventors acted as their own lexicographers and

7 defined the term 'static'" based on the following disclosure in the specification: "The values in the

8 price column are static; *that is*, they do not normally change positions unless a re-centering

9 command is received").

10   The Court rejects DrugLogic's contention that the words "in a preferred case" indicate that

11 the language in this passage merely references a "preferred embodiment." Rather, the Court

12 concludes that the words "in a preferred case" modify the words "for a drug and a reaction system-

13 organ-class." These words do not indicate that the definition provided in this section of the

14 specification applies only to one particular embodiment. In the alternative, even if the term *is*

15 defined in the context of describing a preferred embodiment, the language of the specification makes

16 clear that the inventors were offering a special definition of "analytical drill down" for the '091

17 invention and that definition governs. The Court also rejects DrugLogic's suggestion that the word

18 "then" indicates that the language that follows, relating to analysis performed by the user at different

19 levels of the hierarchy, refers to an "additional step." The only expert testimony in the record on this

20 question is Mr. Jolley's, and he expressed a contrary view, namely, that the user's selection of the

21 level for reanalysis is *part* of "analytical drill down" rather than a subsequent step. *See*

22 DrugLogic's Reply Brief, Ex. A (Jolley Depo.) at 102. He further testified that this language

23 indicated that the user was given the results of the re-analysis in real time. *Id*.

24   Second, while it is undisputed that the term "drill down" had an established meaning at the

25 time of the invention, DrugLogic has offered no evidence that controverts the testimony of Oracle's

26 expert that at the time of the invention the term "analytical drill down" had no established meaning.

27 Nor has DrugLogic offered any expert testimony challenging the testimony of Oracle's expert that

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1 the language in the specification found in column 23 at lines 41-45 would have been understood by a

2 person of ordinary skill in the art as a definition of "analytical drill down."

3   Third, the Court finds unpersuasive DrugLogic suggestion that "analytical drill down" and

4 "drill down" were used interchangeably in the '091 patent as DrugLogic has offered no explanation

5 for the inventor's use of two different terms to convey the same concept.   Further, DrugLogic's

6 position is contradicted by the fact that the passage quoted above begins with the statement that the

7 "invention *also* allows 'analytical drill down.'" '091 patent, col. 23, l. 41 (emphasis added). Given

8 that two examples of "drill down" are described in passages of the specification that precede this

9 statement, *see* '091 patent col. 9, ll. 10-28 and col. 9, l. 66 - col. 10, l. 5, the most logical reading of

10 this statement is that "analytical drill down" is something different from "drill down."

11   The Court also rejects DrugLogic's reliance on *Abbot Labs. v. Andrx Pharms., Inc.*, 473 F.3d

12 1196, 1210 (Fed. Cir. 2007) to support its position that the language in the '091 specification is not

13 definitional. In that case, the Federal Circuit held that the phrase "[t]he pharmaceutically acceptable

14 polymer is a water-soluble hydrophilic polymer" was not an explicit definition of the term

15 "pharmaceutically acceptable polymer" because: 1) the inventors had provided other special

16 definitions in the same patent by explicitly stating that those terms had a special meaning rather than

17 using the more ambiguous "is" construction; 2) neither party's expert offered testimony that the

18 phrase would have been construed as a definition by a person of ordinary skill in the art; and 3) the

19 language of the claims themselves did not support such a construction. None of the reasons that

20 supported the holding in *Abbot Laboratories* applies here. First, as noted above, the language in the

21 '091 specification is not ambiguous but rather, signifies that a definition is being provided; nor has

22 DrugLogic pointed to other definitions in the '091 specification in which clearer language was used

23 to convey that the inventors were offering a special definition. Second, Oracle's expert opined that

24 the language would have been understood as definitional by a person of ordinary skill in the art.

25 Finally, the language of the claims does not suggest that the disclosure in the specification should

26 not be construed as a definition.

27   Finally, the Court finds that Oracle's proposed construction accurately conveys the definition

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of "analytical drill down" set forth in col. 23, lines 41-45 of the '091 patent. Therefore, the Court

construes "allowing analytical drill down" as follows: "allowing a user to redo the analysis in real

time at different levels of the hierarchy."

<div style="text-align:center">

b.   "hyperlinks . . . corresponding to places in an up and down hierarchy"

i.   The Parties' Positions

</div>

DrugLogic's Proposed Construction	Oracle's Proposed Construction
No construction required or "hyperlinks . . . corresponding to subsets of information of more or less specificity relative to one another"	"such links . . . corresponding to different levels of a structured medical dictionary, such as MedDRA"

DrugLogic contends that the term "hyperlinks . . . corresponding to places in an up and down

hierarchy" is readily understandable to a lay jury and therefore requires no construction.

DrugLogic's Opening Brief ('091 patent) at 15 (citing *EON Corp. IP Holdings, LLC v. Sensus USA

Inc.*, 741 F. Supp. 2d 783, 813 (E.D. Tex. 2010)). If the Court finds that construction is necessary,

however, DrugLogic proposes that the term be construed as "hyperlinks . . . corresponding to subsets

of information of more or less specificity relative to one another." *Id*. In support of its position,

DrugLogic quotes an on-line dictionary that includes as one meaning of "hierarchy" "[a]ny system

of . . . things ranked one above another." *Id.*, Ex. 7. DrugLogic also points to the FOLDOC

definition of "hierarchy" as "[a]n organisation with few things, or one thing, at the top and with

several things below each other thing." *Id*., Ex. 8.

According to DrugLogic, Oracle's proposed construction – "such links . . . corresponding to

different levels of a structured medical dictionary, such as MedDRA" – improperly imports

limitations from the specification in limiting the term to hierarchies contained in a "structured

medical dictionary, such as MedDRA." *Id*. Moreover, DrugLogic contends, the specification

supports DrugLogic's broader construction of "hierarchy." *Id*. First, DrugLogic quotes the

following passage, which it argues is a description of one version of the claimed hierarchy:

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> [W]hen a box on a table or in a matrix or a hyperlink is selected, the case listing is generated. When a user clicks on any of the numbers, he/she is provided with a listing of each of the cases corresponding to that link. . . Additionally, if a user wishes to learn the details of a specific case, he/she can click on the case ID number of any specific case on the correlation details screen. This Case Details screen provides detailed information on each specific case.

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Id. at 16 (quoting '091 patent, col. 24, ll. 32-59).

5
    Second, DrugLogic notes that the specification states that "[t]he ability to browse statistics,

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up and down a hierarchy . . . is important to keeping risk assessment hypothesis setting and testing

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within a short period of time." *Id*. at 16 (quoting '091 patent, col. 18, ll. 18-21). This ability is

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depicted in at least three places in Figure 1 of the '091 patent, DrugLogic contends. *Id*. In

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particular, DrugLogic argues that in Figure 1 "the claimed hierarchy is depicted, showing (1) a

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profile or results of a statistical calculation, followed by drilling down to (2) the case list related to

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the calculation, followed by drilling down to (3) the case details for the cases in the list." *Id*.

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DrugLogic also cites to

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the fact that the case details themselves can be structured to be expandable for particular dimensions.

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Id. (citing '091 patent, col. 24, ll. 59-63).

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    According to DrugLogic, "[t]he specification provides that one of these dimensions –

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reaction time – is *preferably* structured in accordance with a structured hierarchical dictionary/

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thesaurus, such as MedDRA." *Id*. at 17 (emphasis supplied by DrugLogic). Specifically, the

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specification provides as follows:

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> For certain dimensions, for example reactions, the hierarchy of the dimension can be selected to change the billboard and detailed views. In the case of reactions, MedDRA contains a five level hierarchy. Other dictionaries use two to four levels. The present invention accommodates the full range of hierarchies.

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Id. (quoting '091 patent, col. 7, ll. 48-54). "Thus," DrugLogic asserts, "while the specification

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discusses that the reaction dimension can be arranged in accordance with a hierarchical structured

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medical dictionary, such as MedDRA, that is not the claimed hierarchy." *Id*.

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    DrugLogic also contends that Oracle's construction makes no sense in the context of the

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claims themselves. *Id*. at 17. In particular, DrugLogic points to the limitation in claims 1 and 8

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requiring that "a last one of the hyperlinks in the up and down hierarchy link[] to a previously-stored

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case describing adverse effects resulting from the use of the at least one drug [substance] of

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interest." *Id*. (quoting claims 1 & 8). The MedDRA hierarchy, however, does not contain any

patient information because it is simply a medical dictionary/thesaurus. *Id*. Further, the last level of

the MedDRA hierarchy is not a previously-stored case; instead, it is the preferred term for a

particular reaction. *Id*. As a result, DrugLogic asserts, if the claimed hierarchy were limited to the

MedDRA hierarchy, as Oracle proposes, it would not satisfy the requirement that the last hyperlink

in the hierarchy is a previously stored case. *Id*.

Finally, DrugLogic relies on the prosecution history in support of its proposed construction.

Id. at 18. In particular, it points to arguments made by the applicant during the application process

emphasizing the importance of the ability to use a hyperlink within the hierarchy to display the

underlying patient case date. *Id*. at 18. In particular, the applicant, Victor Gogolak, argued as

follows:

> One of the features that provides significant improvement over any prior art adverse drug
> effects research systems or other methodologies is the association of the analytical results
> and underlying data with hyperlinks, which are respectively associated with different places
> in a hierarchy….The last portion of the amended claim ["a last one of the hyperlinks in the
> up and down hierarchy linking to a previously stored case"] is particularly important in that
> no matter what type of statistics a user of the system may be viewing, the fundamental or
> underlying data, namely, a particular "case" is always available for display.

Id., Ex. 5 at 11. He further argued that "there is absolutely nothing in [the prior art] that discloses or

even suggests the use of hyperlinks in a hierarchical fashion in which a last one of the hyperlinks

points to a previously stored case describing adverse effects resulting from a given drug of interest."

Id., Ex. 5 at 12.

Oracle argues that DrugLogic's position is incorrect because it fails to take into account the

intrinsic evidence, instead relying on "generic extrinsic dictionary definitions of the term

'hierarchy,' untethered to the context of the '091 patent." Oracle Responsive Brief ('091 patent) at

11. Pointing to its expert's testimony that at the time of the invention the term "up and down

hierarchy" had no ordinary meaning, Oracle contends the meaning of the term would have been

drawn from the claims and specification, which support Oracle's proposed construction. *Id*. at 11-12

(citing Jolley Decl., ¶¶ 22-24).

With respect to claim language, Oracle cites to the language in claims 1 and 8 specifying that

"analytical drill down" is performed by "selectively selecting successive hyperlinks," and that those

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hyperlinks "respectively correspond[] to places in an up and down hierarchy." *Id*. at 12. This language makes clear, according to Oracle, that "analytical drill down" occurs along the "up and down hierarchy." *Id*. Oracle further contends that "[t]his corresponds with the '091 specification's definition of 'analytical drill down' as occurring at different levels of the MedDRA hierarchy." *Id*. Thus, Oracle asserts, the "up and down hierarchy" and the MedDRA hierarchy are "one and the same" and therefore, "places in an up and down hierarchy" should be construed as "levels of a structured medical dictionary, such as MedDRA." *Id*.

Oracle argues that the specification also supports this conclusion because it describes in detail how the invention of the '091 patent makes use of the MedDRA hierarchy. *Id*. For example, the specification describes Figure 7 as follows:

> By utilizing the pull down menu, a user can choose among multiple different levels of MedDRA. . . . In FIG. 7, a user has chosen the HLT option. The window in the pull-down menu indicates that there are 256 HLTs out of the total of 1495 HLTs in the current version of MedDRA. The Reactions Table 702 shows the Top 10 HLTs of the 256.

Id. (quoting '091 patent col. 17, l. 64 - col. 18, l. 23) (emphasis added)). Oracle notes that at the end of this description of "the invention's MedDRA functionality," the specification states as follows:

> The ability to browse statistics, up and down a hierarchy, and within real time, is important to keeping risk assessment hypothesis setting and testing within a short period of time.

Id. (quoting '091 patent, col. 18, ll. 18-20). This is the only place in the patent that the term "up and down hierarchy" appears, and to the extent it is used in connection with the invention's use of MedDRA, Oracle contends, it supports the conclusion that the "up-and-down hierarchy" described in the '091 patent "is a MedDRA-like hierarchy" and therefore, "places in an up and down hierarchy" means "levels of a structured medical dictionary, such as MedDRA." *Id*. at 12-13.

Oracle rejects DrugLogic's position, based on extrinsic evidence, that a hierarchy means simply, "things ranked one above another." *Id*. at 13. According to Oracle, many of the purported examples of hierarchies in the specification that are offered by DrugLogic are not described as hierarchies at all. *Id*. For example, Oracle points out that Figure 1, which DrugLogic cites as an example of a hierarchy, is described in the specification as a "chart indicating the page flow of the present invention." *Id*. (citing '091 patent, col. 7, ll. 58-60). Similarly, the version of the invention

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1   described in column 24 at lines 32-59, on which DrugLogic relies in support of its proposed

2   construction, does not use the word "hierarchy." *Id*. According to Oracle, the word "hierarchy" is

3   used only to refer to the hierarchy of MedDRA or other structured medical dictionaries. *Id*. (citing

4   '091 patent, col. 14, ll. 47-51 ("MedDRA hierarchy Group"); col. 17, ll. 48-53 ("In the case of

5   reactions, MedDRA contains a five level hierarchy."); col. 18, ll.18-22 ("The ability to browse

6   statistics, up and down a hierarchy") (discussed in detail above); col. 20, ll. 1-2 ("The filter is based

7   on the MedDRA hierarchy and begins at the SOC level."); col. 20, ll.12-19 ("For displayed

8   MedDRA leads, preferably a tree is used. When it is collapsed, an open box preferably means no

9   selections lower in the hierarchy have been identified . . . .")).

10   Oracle also rejects DrugLogic's argument that "the up-and-down hierarchy" cannot be

11   limited to a MedDRA-like hierarchy because of the language of claims 1 and 8 relating to "a last one

12   of the hyperlinks . . . linking to a previously-stored case." *Id*. at13-14. According to Oracle, this

13   argument is based on a misreading of the claim language, which does "not require that the lowest

14   level of the hierarchy *be* the previously-stored case; they require only that 'a last one of the

15   hyperlinks in the up and down hierarchy *link[]* to a previously stored case describing adverse effects

16   resulting from the use of the at least one drug of interest." *Id*. (quoting claims 1 & 8)(emphasis in

17   Oracle's brief). Oracle offers the following example to illustrate this point:

18   For example, imagine a user viewing statistics related to the impact of a particular drug on
            the Ear and Labyrinth Disorders SOC. That user could click hyperlinks along the "up and
19   down hierarchy" of MedDRA to view statistics related to the impact of that drug on the
            "painful sensitiveness to sound" LLT. On the LLT page, representing statistics related to a
20   "painful sensitiveness to sound," there could be an additional hyperlink linking to a
            previously stored case in which a patient suffered "painful sensitiveness to sound." That
21   hyperlink would be "a last one of the hyperlinks in the up and down hierarchy," and it would
            "link[] to a previously stored case," as required by the claims.

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23   *Id*. at 14. Oracle contends that this is how DrugLogic's Qscan product operates, as is explained by

24   DrugLogic in a Qscan product demo. *Id*. (citing Von Der Ahe Decl., Ex. M). Because DrugLogic

25   admits that Qscan is an embodiment of the '091 patent, Oracle argues, this evidence supports

26   Oracle's proposed construction. *Id*. at 14-15.

27   In its reply brief, DrugLogic argues that Oracle has mischaracterized the '091 specification

28   by failing to acknowledge the fact that it references not just the MedDRA hierarchy but many

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hierarchies, including hierarchies that pertain to dimensions such as reactions, concomitant drugs, demographics, report dates and outcomes. DrugLogic's Reply Brief ('091 patent) at 7 (citing '091 patent, col. 17, ll. 52-53 ("The present invention accommodates the full range of hierarchies."); col. 24, ll. 59-60) ("If these details are structured, all features of the invention are expandable to that dimension.")). DrugLogic contends that Oracle's expert conceded this point. *Id*. (citing DrugLogic's Reply Brief ('091 patent), Ex. A (Jolley Depo.)). DrugLogic further contends that its position is supported by disclosure in the specification making clear that the user can build his or her own hierarchies. *Id*. (citing '091 patent, col. 14, ll. 16-20 ("[i]n addition, the invention provides the ability to develop specific other taxonomies, such as a 'super generic' including all salts of a drug, or a sub-brand, for example distinguishing between once a day version of a drug from once a week version of a drug"); col. 15, ll. 40-51 (describing how a user can search using various categories, including "custom-defined categories"); col. 16, ll. 1-2 (reference to "custom-designed categories"); col. 17, ll. 55-56 (same); col. 20, ll. 35-53 (describing filters that can be included in various embodiments of the invention, including filters for dimensions such as demographics, drug birth date and outcomes, and noting that "if a custom seriousness set is defined, this dimension will be user definable"). Oracle's proposed construction would improperly exclude these disclosed hierarchies, DrugLogic argues. *Id*. In contrast, DrugLogic asserts, its own proposed construction would include all of the hierarchies disclosed in the specification and comports with the ordinary meaning of the word "hierarchy," which Oracle's expert conceded means "something with layers" or "some entity with levels." *Id*. at 8 n. 12 & Ex. A (Jolley Dep.) at 33-35.

Similarly, DrugLogic argues that many of the references to the MedDRA hierarchy are offered as examples, further supporting the conclusion that the inventor did not limit his invention to the MedDRA hierarchy. *Id.* at 8 (citing '091 patent, col. 17, ll. 48-51 ("[f]or certain dimensions, for example reactions, the hierarchy of the dimension can be selected to change the billboard and detailed views. In the case of reactions, MedDRA contains a five level hierarchy"); col. 14, ll. 40-51 (identifying "an example" of the results of a saved filter showing a drug's reactions); col. 17, ll. 57-61 ("With regard to the Reactions dimension, the profiled component of the present invention preferably shows reactions to the drug that is being queried"); col. 19, l. 66 - col. 20, l. 2 (discussing

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1 Fig. 12's depiction of a filter based on the MedDRA hierarchy as "[a]n exemplary filter")).

2 DrugLogic challenges Oracle's argument that the MedDRA hierarchy satisfies the

3 requirement of claims 1 and 8 that the last hyperlink must link to a case, arguing that this

4 requirement is not satisfied under Oracle's construction because the specification only describes

5 MedDRA as a means to filter data and display statistical results. *Id*. at 8-9. Further, DrugLogic

6 asserts, Oracle's reliance on DrugLogic's Qscan product is misplaced. First, because that product is

7 only an embodiment of the invention, DrugLogic argues, it cannot form the basis of any claim

8 construction. *Id.* at 9 n. 15 (*citing Int'l Vision Corp. v. Crown Metal Manufacturing Co.*, 991 F.2d

9 768, 771-772 (Fed. Cir. 1993)). Second, DrugLogic contends that "clicking on the last hyperlink in

10 the MedDRA hierarchy in Qscan will only display the statistical results for that level of MedDRA

11 hierarchy." *Id*. at 9. According to DrugLogic, "[i]t is not until the user clicks on the hyperlink for

12 the statistical result (a hyperlink that is not *in* the MedDRA hierarchy) that the hierarchy called for

13 by the claim is implicated." *Id*.

14 DrugLogic contends that its proposed construction is consistent with the specification's

15 description of how the hierarchy in the invention can be used, which "describes how a user can click

16 on a hyperlink associated with a statistical analysis to get to a case list and can then click on another

17 hyperlink associated with that case list to be taken to a previously stored case." *Id*. (citing '091

18 patent, col. 24, ll. 32-50). According to DrugLogic "this hierarchy of data is the hierarchy that is

19 contemplated by the 'wherein' clause as it describes how the user can click on successive hyperlinks

20 to go to the case details." *Id*. DrugLogic further contends that this hierarchy is described repeatedly

21 throughout the specification. *Id*. (citing '091 patent, Fig. 1 at reference numerals 105-107, 108-110

22 and 112-114; col. 24, ll. 32-50; col. 9, ll.10-29; and col. 10, ll. 4-5).

23 **ii.   Analysis**

24 As discussed above, a claim term should be given its ordinary meaning as it would be

25 understood by a person skilled in the art at the time of the invention who has read the specification

26 and is familiar with the prosecution history. Although Oracle challenges DrugLogic's reliance on

27 extrinsic evidence for its definition of the word "hierarchy," the parties do not disagree in any

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United States District Court
For the Northern District of California

meaningful way about the meaning of that word, standing on its own.[4] The more difficult question is whether the claim term "hyperlinks . . . corresponding to places in an up and down hierarchy" refers to a more limited set of hierarchies. Based on the disclosure in the specification, the Court concludes that this claim term requires construction because the generic meaning of "hierarchy" is broader than the meaning of "up and down hierarchy" in the '091 claims. Further, the Court agrees with Oracle that the "up and down hierarchy" refers to MedDRA or some other structured medical dictionary.

Read together, the claims and the specification support Oracle's proposed construction. As to the claims, the language of the Wherein Clause, in claims 1 and 8, supports the conclusion that "analytical drill down" occurs along the "up and down hierarchy," providing that "analytical drill down" is performed by "selectively selecting successive hyperlinks" that "correspond[] to places in an up and down hierarchy." Thus, the description of analytical drill down in the specification sheds light on the meaning of "up and down hierarchy."   The Court finds particularly significant the passage of the specification found at col. 17, l. 34 - col. 18, l. 22.   In that passage, the patentees explain that "[t]he profile feature of the present invention is used to display statistics that describe the effects of the drug in multiple dimensions." '091 patent, col. 17, ll. 34-35. The specification offers as an example "reactions," noting that in MedDRA the hierarchy contains five levels for reactions. '091 patent, col. 17, ll. 50-51. It goes on to state that "[o]ther dictionaries contain two to four levels" and that the invention "accommodates the full range of hierarchies." '091 patent, col 17, ll. 51-53. Finally, the passage states that this "ability to browse statistics, *up and down a hierarchy*, and within real time, is important to keeping risk assessment hypothesis setting and testing within a short period of time." '091 patent, col. 18, ll. 18-20 (emphasis added). This passage supports the conclusion that an "up and down hierarchy" is a structured medical dictionary, of which MeDRA is one example.

Although DrugLogic cites to disclosure in the specification that the user can define his or her own classes or dimensions, it does not point to any discussion in the specification indicating that

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[4]As stated above, DrugLogic contends the word means "a system of . . . things ranked one above the other," while Oracle's expert testified that a hierarchy is "something with layers."

these classes or dimensions would themselves be components of the "up and down hierarchy."   Nor is the Court persuaded by DrugLogic's argument that Figure 1 of the '091 patent provides examples of "up and down hierarchies."   Although Figure 1 illustrates how the invention allows the user to "drill down" to obtain case details, the description of this figure does not identify these steps as being part of the "up and down hierarchy" described in the claims.   *See* '091 patent, col. 8, l. 62 - col. 9, l. 50.   Rather, the specification describes Figure 1 as a "chart indicating the page flow of the present invention."   '091 patent, col. 7, ll. 58-60.   Similarly, the passage found at col. 24, ll. 32-59, which DrugLogic contends describes a version of the "up and down hierarchy," does not contain the word "hierarchy."

Further, the Court rejects DrugLogic's contention that MedDRA and other structured medical dictionaries do not satisfy the requirement in claims 1 and 8 that the last hyperlink in the hierarchy must link to a previously stored case.   Rather, the Court finds that Oracle is correct in its assertion that the last hyperlink in the up and down hierarchy of MedDRA or other dictionaries can link to previously stored cases and thus satisfy this limitation.   As the Court finds nothing in the specification that suggests that the case information must be the bottom level of the "up and down hierarchy," the Court rejects DrugLogic's position.

Accordingly, the Court construes "hyperlinks . . . corresponding to places in an up and down hierarchy" as follows: "such links . . . corresponding to different levels of a structured medical dictionary, such as MedDRA."

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     c.   **"associating respective hyperlinks with a plurality of portions of such data and analysis"**

2

     i.   **The Parties' Positions**

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DrugLogic's Proposed Construction	Oracle's Proposed Construction
"generating hyperlinks corresponding to subsets of the information reflecting the risks of adverse effects and the statistical analysis"	**Initial**: "creating a plurality of links within web pages for some of the previously stored information and some of the results of the statistical analysis such that clicking on the information or results causes a user to jump to another web page" **Modified**: "creating a plurality of links within web pages for some of the previously stored information and some of the results of the statistical analysis such that clicking on the information or results causes a user to jump to another place in the same web page or to an entirely different web page"

14   DrugLogic's proposed construction of "associating respective hyperlinks with a plurality of

15 portions of such data and analysis" is "generating hyperlinks corresponding to subsets of the

16 information reflecting the risks of adverse effects and the statistical analysis." According to

17 DrugLogic, the plain meaning of the word "associate" supports its proposed construction.

18 DrugLogic Opening Brief ('091 patent) at 13-14. DrugLogic quotes the following dictionary

19 definition of the word "associate": "to join or connect together; to bring together or into relationship

20 in any of various intangible ways . . ." *Id*., Ex. 6 (print-out from on-line version of Merriam-

21 Webster Dictionary). Thus, DrugLogic contends, "[i]n the context of the claim, associate means to

22 connect two pieces of information (whether, for example, data regarding adverse events or the

23 statistical analysis) such that the user can get from one piece of information to another." *Id*. at 14.

24   DrugLogic also points to the following passage in the specification in support of its proposed

25 construction:

26   Another important aspect of the web-based analysis . . . is the ability to associate hyperlinks
        with each piece of data. For example, within the application, it is possible to link each
27   number, name, entry, and selectable point with additional information.

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1   *Id*. (quoting '091 patent, col. 13, ll. 36-42). According to DrugLogic, this passage indicates that

2   "data can be linked to other data, results can be linked to data, data can be linked to results, results

3   can be linked to results, etc." *Id*.

4   DrugLogic argues that Oracle's proposed construction[5] is incorrect for two reasons. First, it

5   contends that Oracle's construction "is not based on the plain meaning of the words of the claim or

6   the specification [because] [a]ssociating hyperlinks with the data and analysis simply means that the

7   data and analysis are related to each other or other information via a hyperlink generated by the

8   system." *Id*. at 13. Second, DrugLogic argues that Oracle's proposed construction is incorrect to the

9   extent it requires that the hyperlinks link to a separate web page. *Id*. at 14. DrugLogic contends that

10   this language also applies to hyperlinks that link to another location on the same web page. *Id*.

11   According to Oracle, the main dispute between the parties is "whether 'associating

12   hyperlinks' with 'portions of [] data and analysis' means making those 'portions of []data and

13   analysis *into* clickable hyperlinks' (Oracle's proposed construction), or whether it means something

14   much more vague: 'generating hyperlinks corresponding to subsets of information reflecting the risk

15   of adverse effects and the statistical analysis.' (DrugLogic's proposed construction.)" Oracle

16   Responsive Brief ('091 patent) at 15.

17   Oracle argues that its proposed construction is supported by the specification, citing the same

18   passage upon which DrugLogic relies, col. 13 at lines 37-42 (quoted above). *Id*. at 16. According to

19   Oracle, this passage means that "to 'associate' a hyperlink with a piece of data, in this patent, means

20   to 'link' that piece of data with additional information by turning the piece of data into a hyperlink."

21   *Id*. Oracle also points to two figures that it contends illustrate such hyperlinks, Figures 13 and 19.

22   Figure 13 depicts "an exemplary screen presenting the results of a correlated search." '091 patent,

23   col. 21, ll. 23-24. The search results are ranked according to the strength of the correlation and "a

24   user is preferably presented hyperlinks comprising all of the numbers in the Rank column." '091

25   patent, col. 21, l. 67 - col. 22, l. 2. "These hyperlinks provide a link to individual case lists." '091

26   patent, col. 22, ll. 3-5. "Figure 19 is the tabular presentation of the proportional analysis results."

27   [5]At the time DrugLogic filed its opening brief, Oracle's proposed construction was the initial
28   construction quoted above.

1   '091 patent, col. 23, ll. 53-54. Two of the columns show the correlated terms, while a third shows

2   the reaction "count." '091 patent, col. 31, ll. 54-62. Two additional columns list the "expected

3   reaction count" and the "relative ratio." *Id*. The specification explains that the reaction count

4   numbers are "hyperlinked to the case-list." '091 patent, col. 23, ll. 65-66. Finally, Oracle points to

5   the statement in the specification that "if a user wishes to learn the details of a specific case, he/she

6   can click on the case ID number of any specific case on the correlation details screen." Oracle's

7   Responsive Brief ('091 patent) at 16 (citing '091 patent, col. 24, ll. 46-48).

8   Oracle also cites the prosecution history in support of its proposed construction, pointing to

9   the following argument made by Mr. Gogolak in support of patentability:

10   One of the features that provides significant improvement over any prior art . . . is the
    association of analytical results and underlying data with hyperlinks, which are respectively

11   associated with different places in a hierarchy.

12   Von Der Ahe Decl., Ex. K at 11. According to Oracle, this "explains that analytical results and

13   underlying data are made into hyperlinks, and that those hyperlinks, in turn, point to different places

14   in a hierarchy." Oracle's Responsive Brief ('091 patent) at 16.

15   Oracle argues that DrugLogic's proposed construction makes no sense because it reasons,

16   based on the definition of "associate," that "associating . . . hyperlinks with . . . portions of such data

17   and analysis" means "to join or connect two pieces of information . . . such that the user can get from

18   one piece of information to another." *Id.* (quoting DrugLogic's Opening Brief ('091 patent) at 14).

19   According to Oracle, this reasoning does not follow from the language of the claims because "it is

20   the *hyperlink* that is associated with a piece of information, not pieces of information that are being

21   associated to one another." *Id*.

22   In response to DrugLogic's contention that Oracle's proposed construction incorrectly

23   requires that the hyperlink take a user to a different web page, Oracle modifies its proposed

24   construction to allow for hyperlinks that permit the user to jump to a different location on the *same*

25   page, proposing the following construction:

26   creating a plurality of links within web pages for some of the previously stored information
    and some of the results of the statistical analysis such that clicking on the information or

27   results causes a user to jump to another place in the same web page or to an entirely different
    web page.

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Id. at 17. Oracle contends that this proposed construction is consistent with the parties' agreement that "such data and analysis" shall be construed to mean "previously stored information reflecting occurrences of adverse events and results of the statistical analysis." *Id.* n. 5 (citing Von Der Ahe Decl., Ex. B (Amended Joint Claim Construction and Prehearing Statement) at 3).

In its reply brief, DrugLogic argues that there is no support for limiting this claim term to a particular method of "associating . . . hyperlinks . . .with . . .data and analysis." DrugLogic's Reply Brief ('091 patent) at 5-6. Rather, "so long as both the anchor and target pages include portions of the data and analysis, then such portions of data and analysis are 'associated' with the hyperlink." *Id.* at 6. According to DrugLogic, Oracle's proposed construction impermissibly adds a limitation that is not found in either the intrinsic or extrinsic evidence.

At oral argument, DrugLogic acknowledged that one way to satisfy this claim term is to turn the data or analysis itself into hyperlinks. It argued, however, that the claim term is not *limited* to this manner of associating hyperlinks with data or analysis. In support of this position, DrugLogic argued, for the first time, that Figure 13 (cited in Oracle's responsive claim construction brief) does not support Oracle's proposed construction but instead reflects an "association" of a hyperlink to data or analysis that is *not* accomplished by turning the actual data or analysis into a hyperlink. In particular, DrugLogic argues that the rankings in the Rank column in that figure are not "analysis or data." It is these numbers, however, that are turned into hyperlinks in order to permit a user to obtain stored information about the underlying cases. Similarly, DrugLogic asserted (again, for the first time), Figure 14 depicts an "association" of hyperlinks to data or analysis in which the association is not achieved by turning the data or analysis itself into hyperlinks. Rather, according to DrugLogic, the Case Id. numbers are turned into hyperlinks. Oracle countered that DrugLogic's position was contradicted by the passage in the specification quoted above, found at col. 13, ll. 38-41 of the '091 patent ("For example, within the application, it is possible to link each number, name, entry and selectable point with additional information.")

ii.   Analysis

The dispute as to this claim term turns on the nature of the claimed "association" between the "hyperlink" and "such data and analysis." Is the data and analysis that is referred to in the claim as "such data and analysis" actually turned into a hyperlink (as Oracle contends) or can the hyperlink be "associated" with that data and analysis in other ways as well (as DrugLogic contends)? Although the words of the claim itself are ambiguous as to the meaning of the word "associate," the Court finds that the specification and prosecution history support Oracle's position that this claim term requires that the data and analysis must be turned into hyperlinks.

First, in the specification, the inventors describe the ability of the invention to associate hyperlinks "with each piece of data" and offer as examples the ability of the invention to "link each number, name, entry, and selectable point with additional information." '091 patent, col. 13, ll. 36-42. In other words, the "data" itself is "link[ed]" to other information; moreover, the inventors indicate that "number[s], name[s], entr[ies] and selectable point[s] are all examples of "data." Further, Figures 13 and 19 depict data items and analysis that have been made into hyperlinks. In particular, in Figure 13 the numbers that indicate Rank are hyperlinks, and in Figure 19, the reaction count numbers are turned into hyperlinks.

Second, the arguments made during the prosecution history support the conclusion that the words "associating . . . hyperlinks with . . . such data and analysis" mean turning the data and analysis into hyperlinks. In particular, the inventor stated that "[o]ne of the features that provides significant improvement over any prior art . . . is the association of analytical results and underlying data with hyperlinks, which are respectively associated with different places in a hierarchy." *See* Von Der Ahe Decl., Ex. K at 11.

The Court is not persuaded by DrugLogic's argument, raised for the first time at the claim construction hearing, that Figures 13 and 14 support a contrary result to the extent that the Rank numbers in Figure 13 and the Case Ids. in Figure 14 are turned into hyperlinks.[6] The premise of

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[6]This argument should have been raised in DrugLogic's opening or reply claim construction briefs. DrugLogic's failure to raise this argument in its briefs is particularly troubling because Oracle expressly asserted in its responsive claim construction brief that Figure 13 *supported* its proposed

1   DrugLogic's argument is that Rank numbers and Case Ids. are not "data" or "analysis," and

2   therefore, to the extent that these figures illustrates the association of hyperlinks with "such data and

3   analysis,"[7] that claim term cannot be limited to a method whereby the data and analysis is *itself*

4   turned into hyperlinks. DrugLogic relies in part on the parties' agreement that "such data and

5   analysis" means "previously stored information reflecting occurrences of adverse events and results

6   of the statistical analysis." Rank numbers and Case Ids. do not fall within this definition, DrugLogic

7   asserts, because they do not reflect occurrences of adverse events and results of statistical analysis.

8   The language of the parties' construction of "such data and analysis" is itself ambiguous, however.

9   For example, the Case Id.s might be considered part of the stored information reflecting occurrences

10   of adverse events because they correspond to a data set reflecting such occurrences. Further, the

11   Rank numbers in Figure 13 are essentially analysis in that they rank the scores that are associated

12   with pairs of terms. At oral argument, DrugLogic acknowledged that the "score" was the "analysis."

13   Rather than engage in an exercise of trying to parse the meaning of the words used by the parties in

14   their stipulated construction, the Court finds that it is sufficient that that construction can be

15   reconciled with the Court's construction of the claim term as a whole, based on its reading of the

16   claims in light of the specification and prosecution history.

17   Accordingly, the Court adopts Oracle's proposed construction. The term "associating

18   respective hyperlinks with a plurality of portions of such data and analysis" is construed as follows:

19   "creating a plurality of links within web pages for some of the previously stored information and

20   some of the results of the statistical analysis such that clicking on the information or results causes a

21   user to jump to another place in the same web page or to an entirely different web page."

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25   construction. DrugLogic did not respond to that argument in its reply brief. On that basis, DrugLogic

26   arguably waived this argument. Nevertheless, in the interest of construing this claim term in a manner
     that is consistent with its usage in the specification, the Court considers the argument on the merits.

27   [7]At oral argument, the parties did not dispute that these figures provide examples of the claimed

28   hyperlinks.

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2.   Other Disputed Claim Terms in Claims 1 and 8

a.   "permitting the at least one remote user to analyze safety issues"

DrugLogic's Proposed Construction	Oracle's Proposed Construction
"permitting the at least one remote user to use statistical analysis to study safety issues"	"permitting the at least one remote user to run a statistical analysis that finds 'signals' such as anomalies in a random population, changes against a known background, or coherent targets in a noise background"

i.   The Parties' Positions

According to DrugLogic, the parties agree that this term means "permitting the at least one remote user to use statistical analysis" but disagree as to the meaning of the phrase "to analyze safety issues." DrugLogic's Opening Brief ('091 patent) at 12. DrugLogic contends that Oracle's proposed construction improperly limits the way safety issues must be analyzed, namely, by requiring that safety issues must be analyzed by "finding signals." *Id*. This approach should be rejected, DrugLogic asserts, because it violates the doctrine of claim differentiation, which provides that where a particular limitation is included in a dependent claim, a presumption arises that that limitation is not found in the independent claim. *Id*. (citing *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007)). Here, DrugLogic points out, the limitation proposed by Oracle is found in dependent claims 15 and 16, which depend from claims 1 and 8, respectively. *Id*. In fact, DrugLogic contends, this additional limitation is the "only meaningful difference" between independent claims 1 and 8 and dependent claims 15 and 16. *Id*. DrugLogic further asserts that Oracle's violation of the doctrine of claim differentiation is "particularly glaring because the meaning of the phrase 'to analyze safety issues' is readily apparent." *Id*. That meaning is evident, DrugLogic argues, from dictionary definitions of the word "analyze." *Id*. at 12-13 and Ex. 6 (Excerpts from Merriam-Webster's Online Dictionary, www.merriam - webster.com (2012)) (defining "analyze" as "to study…the nature and relationship of the parts of by analysis"); Ex. 7 (excerpt from Dictionary.com, www.dictionary.reference .com (2012)) (defining "analyze" as "(2) to

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1   examine critically…; (3) to examine carefully and in detail so as to identify causes, key factors,

2   possible results, etc.; (4) to subject to mathematical . . . analysis").

3   DrugLogic acknowledges that the specification of the '091 patent "discusses that the

4   invention assists safety groups with 'determining "signals" that indicate a relationship among

5   adverse reactions, demographics, and other elements such as outcomes.'" *Id.* at 13 (citing '091

6   patent, col. 6, ll. 11-35). This passage, however, does not support Oracle's proposed construction,

7   DrugLogic argues, because "[t]he fact that a patent asserts that an invention achieves several

8   objectives does not require that each of the claims be construed as limited to structures that are

9   capable of achieving all of the objectives." *Id.* (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358

10 F.3d 898, 908 (Fed. Cir. 2004)).

11 Oracle responds that the presumption of claim differentiation is rebuttable and that it is

12 rebutted here. Oracle Responsive Brief ('091 patent) at 17 -18 (citing *Marine Polymer Techs., Inc.*

13 *v. HemCon, Inc.*, 672 F.3d 1350, 1359 (Fed. Cir. 2012)). In particular, Oracle points to the

14 following passage in the specification, which Oracle contends expressly limits the scope of the

15 invention:

16   The analysis provided by the system and method of the present invention finds "signals"
        such as anomalies in a random population, a change against a known background, or a
17   coherent target in a noise background.

18 *Id.* (quoting '091 patent, col. 20, ll. 54-57). According to Oracle, this language "does not merely

19 describe a preferred embodiment of the invention – it describes *the* 'present invention.'" *Id.* at 18

20 (emphasis in original). Therefore, Oracle contends, this feature must be included in the Court's

21 construction of this claim term. *Id.* (citing *Netcraft Corp. v. eBay, Inc.*, 549 F.3d 1394, 1398 (Fed.

22 Cir. 2008); *Verizon Services Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1308 (Fed. Cir.

23 2007)).

24 DrugLogic argues in its reply brief that the language in the specification cited by Oracle

25 "merely references one aspect or advantage" of the invention and the Court must give the claim term

26 the full range of its ordinary meaning. DrugLogic's Reply Brief ('091 patent) at 5 (citing *Kim v.*

27 *ConAgra Foods, Inc.*, 465 F.3d 1312, 1319 (Fed. Cir. 2006); *Howmedica Osteonics Corp. v. Wright*

28 *Med. Tech., Inc.*, 540 F.3d 1337, 1345 (Fed. Cir. 2008)). DrugLogic reiterates it position that the

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1   doctrine of claim differentiation supports its proposed construction, citing this Court's decision in

2   *Augme Techs., Inc. v. Yahoo!, Inc.*, 2011 U.S. Dist. LEXIS 109886 at *48-51 (N.D. Cal. Sept. 27,

3   2011).

ii.   Analysis

5   The question facing the Court is whether the language in the specification describing the

6   "present invention" limits the meaning of the phrase "to analyze safety issues" in claims 1 and 8,

7   even though such a construction would give rise to a result that is generally disfavored in claim

8   construction, namely, that claims 15 and 16 would claim essentially the same subject matter as

9   claims 1 and 8, respectively. The Court concludes that it does.

10   The doctrine of claim differentiation "stems from 'the common sense notion that different

11   words or phrases used in separate claims are presumed to indicate that the claims have different

12   meanings and scope.'" *Seachange Intern., Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1368 (Fed. Cir.

13   2005) (quoting *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999)).

14   In *Seachange*, the Federal Circuit explained that the doctrine is "at its strongest" where, as here,

15   "'the limitation sought to be "read into" an independent claim already appears in a dependent

16   claim.'" *Id*. at 1369 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910

17   (Fed.Cir.2004)). The doctrine only creates a presumption, however, and is not "'a hard and fast rule

18   of construction.'" *Id*. (quoting *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir.

19   2000)). The doctrine of claim differentiation cannot "'broaden claims beyond their correct scope,

20   determined in light of the specification and the prosecution history and any relevant extrinsic

21   evidence. . . .'" *Id*. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480

22   (Fed.Cir.1998)). As a result, "claims that are written in different words may ultimately cover

23   substantially the same subject matter." *Id*.

24   The fact that a preferred embodiment (or even all of the preferred embodiments) described in

25   the specification possesses a feature corresponding to the requested limitation is not sufficient to

26   rebut the presumption of claim differentiation. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800,

27   805-806 (Fed. Cir. 2007) (holding that claim term should not be construed narrowly based on a

28   feature in a preferred embodiment where such a construction would give a dependent claim the same

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For the Northern District of California

1 meaning as the independent claim). Similarly, language in the specification describing the "object"

2 or purpose of an invention has been held insufficient to overcome the presumption of claim

3 differentiation. *E-Pass Technologies, Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369-1370 (Fed. Cir.

4 2003) ("An invention may possess a number of advantages or purposes, and there is no requirement

5 that every claim directed to that invention be limited to encompass all of them"); *see also*

6 *Howmedica Osteonics Corp. v. Wright Medical Technology, Inc.,* 540 F.3d 1337, 1345 (Fed. Cir.

7 2008) (rejecting limitation that was offered on the basis of purposes of the invention in the

8 specification because "[t]he court's task is not to limit claim language to exclude particular devices

9 because they do not serve a perceived 'purpose' of the invention").

10 On the other hand, the presumption that arises under the doctrine of claim differentiation may

11 be rebutted where the specification includes a description of "the present invention" and this

12 language, when read in the context of the claims, specification and prosecution history, describes the

13 invention as a whole. *Netcraft Corp. v. eBay, Inc*., 549 F.3d 1394, 1398 (Fed. Cir. 2008) (holding

14 that language describing "present invention," when read in light of the specification and prosecution

15 history, described entire invention and therefore had to be reflected in claim constructions). For

16 example, in *Verizon Services Corp. v. Vonage Holdings Corp.*, the Federal Circuit addressed the

17 meaning of the claim term "localized wireless gateway system." 503 F.3d 1295, 1308 (Fed. Cir.

18 2007). The court noted that "[i]n the course of describing the 'present invention,' the specification

19 then states that '[t]he gateway compresses and decompresses voice frequency communication

20 signals and sends and receives the compressed signals in packet form via the network.'" *Id.* (citation

21 omitted). The court concluded that this description limited the scope of the invention as a whole and

22 on that basis concluded that the term "localized wireless gateway system" "must be limited to one

23 performing compression and packetization functions at the gateway." *Id*.

24 The Federal Circuit's decision in *Yoon Ja Kim v. ConAgra Foods, Inc*., 465 F.3d 1312 (Fed.

25 Cir. 2006), cited by DrugLogic, also illustrates these rules. In that case, the court construed the term

26 "potassium bromate replacer." *Id*. at 1318. It concluded that the construction should include a

27 limitation requiring that the potassium bromate replacer must be "functional" on the basis of the

28 following language in the specification: "the present invention is particularly useful [in] that it

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1 provides natural ascorbic acid as the only oxidizing agent in dough that is effective and functional

2 throughout the entire manufacturing process." *Id.* (quoting patent). The Federal Circuit held that

3 "[w]hen the claim limitation is read against this backdrop, it is clear that the potassium bromate

4 replacer must be functional." *Id.*

5   On the other hand, the Federal Circuit rejected a more limited construction of "potassium

6 bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing

7 process." *Id.* at 1319. The court stated that "[t]he mere fact that one object of the invention is to

8 produce a slow acting oxidant which is functional throughout the entire manufacturing process does

9 not mean that this particular feature was adopted as a limitation in each claim of the patent." *Id.* It

10 explained further:

11   The specification does not require that the potassium bromate replacer must necessarily be a
         slow acting oxidant, only that particular potassium bromate replacers perform that function. .

12   . .Thus the fact that the patent here discloses the advantages of a slow acting oxidant does not
         mean that all the claims are directed to such an oxidant. *See E-Pass Tech., Inc. v. 3Com*

13   *Corp.*, 343 F.3d 1364, 1368-69 (Fed. Cir. 2003). Indeed, Kim chose to claim a "slow acting"
         oxidant in dependent claim 7, while her independent claims were directed to a more general

14   potassium bromate replacer. The doctrine of claim differentiation suggests that the
         independent claims here should not include explicit limitations of a dependent claim.

15

16 *Id.*

17   Here, the language in the specification does not merely describe an advantage of the

18 invention or a feature of a preferred embodiment. Rather, it categorically states that "[t]he analysis

19 provided by the system of the present invention finds 'signals' such as anomalies in a random

20 population, a change against a known background, or a coherent target in a noise background." '091

21 patent, col. 20, ll. 54-57. Because nothing in the specification or prosecution history supports a

22 contrary conclusion, and based on the clear language in the specification, the Court concludes that

23 this language describes the entire invention and therefore, that Oracle's proposed construction is

24 correct.[8] Therefore, the Court construes the term "permitting the at least one remote user to analyze

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26   [8]DrugLogic's reliance on this Court's decision in *Augme Techs., Inc. v. Yahoo!, Inc.* is
    misplaced. *See* 2011 U.S. Dist. LEXIS 109886 at *48-51 (N.D. Cal. Sept. 27, 2011). In *Augme*, the

27 Court explained that while the specification contained "present invention" language describing the
    function of the invention in terms of "media appliance metaphors," it also contained an express

28 disclaimer stating that the invention was not limited to media appliance metaphors. As noted above,

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1 safety issues" as follows: "permitting the at least one remote user to run a statistical analysis that

2 finds 'signals' such as anomalies in a random population, changes against a known background, or

3 coherent targets in a noise background."

4   **b.   "permitting at least one remote user to access such data through the World Wide Web"**

DrugLogic's Proposed Construction	Oracle's Proposed Construction
"permitting a user at one computer to access the information reflecting occurrences of adverse events on a different computer or server through a collection of web pages containing hyperlinks to other web pages and transmitted using TCP/IP or HTTP protocols"	"permitting a user on one network to access the previously stored information residing on a different network through a series of Internet servers using a standard Web browser, without using special software or downloads"

10   **i.   Parties' Positions**

11   DrugLogic identifies two disputes relating to this claim term: "1) whether a user must access

12 data on a different computer or on an entirely distinct network to be considered a 'remote user,' and

13 2) whether 'through the World Wide Web' means accessing data through a 'standard Web browser,

14 without using special software or download' or simply through 'a collection of web pages containing

15 hyperlinks to other web pages and transmitted using TCP/IP or HTTP protocols.'" DrugLogic's

16 Opening Brief ('091 Patent) at 8.

17   Regarding the meaning of "remote user," DrugLogic argues that the ordinary meaning of this

18 term is "an individual 'who works on a computer from a remote location.'" *Id*. (quoting Tech Terms

19 Computer Dictionary, www.techterms.com (2012)) & Ex. 2. This definition finds further support in

20 the specification, DrugLogic contends. *Id*. at 8-9. In particular, the specification provides that "[a]

21 web browser makes a connection via the WWW to other computers known as web servers, and

22 receives information from the web servers that is displayed on the user's workstation." *Id*. at 9

23 (quoting '091 patent, col. 10, ll. 39-42). DrugLogic also points to the following passage in the

24 specification:

25   The web-based aspect of the assessment of adverse effects of one or more drugs of the
         present invention also permits multiple simultaneous users. This feature of the present

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28 the specification of the '091 patent contains no such language or disclaimer.

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1 invention is important in assessors who, although working for the same organization are in
2 different locations.

3 *Id*. (quoting '091 patent, col. 13, ll. 10-15).

4 DrugLogic further contends that Oracle's proposed construction is incorrect to the extent that

5 it requires that a remote user utilize a different network because it contradicts the specification.

6 DrugLogic Opening Brief ('091 Patent) at 9. DrugLogic quotes the following passages it contends

7 shows that users of the invention may communicate over a single network:

8 Networks for personal computers were developed to allow individual users to communicate
with each other. In this manner, a large number of people within a company could
9 communicate simultaneously over *a network* with a software application running on a single
computer system.
10

11 *Id*. (quoting '091 patent, col. 10, ll. 24-29) (emphasis in DrugLogic's brief).

12 The Web permits web-based applications. Such web-based applications use TCP/IP and
HTTP protocols to transport information from a *central network application server* to Web
13 clients and back.

14 *Id*. (quoting '091 patent, col. 5, l. 66-col. 6, l. 2) (emphasis in DrugLogic's brief) .

15 Although numerous system architectures may be used to implement the inventive technique,
one particularly advantageous architecture is implemented, for example, in a corporate
16 enterprise (such as an intranet), wherein a plurality of client machines (desktops) interface
with a support center located at a server node through a network.
17

18 *Id*. (quoting '091 patent, col. 11, ll. 45-51).

19 With respect to the meaning of "through the World Wide Web," DrugLogic argues that its

20 proposed construction – which does not require that the invention work with a standard web browser

21 and without the use of special software – is supported by the specification. *Id*. at 9. DrugLogic

22 points to the following passages in the specification:

23 The World Wide Web is a system of Internet servers that support specially formatted
documents. The documents are formatted in a language called HTML…that supports links to
24 other documents…. This means a user can jump from one document to another simply by
clicking on hot spots.
25

26 *Id.* (quoting '091 patent, col. 5, l. 56 - col. 6, l. 5).

27 T]he Internet grew out of the modern proliferation of computers and networks, and has
evolved into a sophisticated worldwide network of computer systems linked together by web
28 pages that collectively make up the "world wide web[.]"

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Id. at 10 ('091 patent, col. 10, ll. 32-36).

> The Web permits web-based applications. Such web-based applications use TCP/IP and HTTP protocols to transport information from a central network application server to Web clients and back.

Id. (quoting '091 patent, col. 5, l. 66 - col. 6, l. 2).

DrugLogic also cites extrinsic evidence in support of its proposed construction, namely, the following description of the World Wide Web on Webopedia, which describes the World Wide Web as follows:

> The [World Wide] Web uses the HTTP protocol, only one of the languages spoken over the Internet, to transmit data. Web services, which use HTTP to allow applications to communicate in order to exchange business logic, use the Web to share information. TheWeb also utilizes browsers, such as Internet Explorer or Firefox, to access Web documents called Web pages that are linked to each other via hyperlinks.

Id. & Ex. 3 (Webopedia, www.webopedia.com, (2012)). DrugLogic also quotes the Federal Circuit, which has stated:

> The World Wide Web, a collection of files, or "web pages," containing text, graphics, audio, and video, as well as "hyperlinks" to other web pages, has become a central part of the Internet. Consumers typically access the web using client software applications known as web browsers that run on their personal computers.

Id. (quoting *Resonate, Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1361 (Fed. Cir. 2003)).

DrugLogic concedes that the specification contains language that tracks Oracle's proposed construction, stating that "the web-based analysis of adverse drug effects of the present invention further permits the application to be run from a server and accessed by standard browsers, thus obviating the need for special software or downloads." *Id*. (quoting '091 patent, col. 6, ll. 55-59). However, DrugLogic contends that this language does not require that standard Web browsers be used or that special software or downloads be excluded because it merely sets forth an advantage of the invention. *Id*. (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005)). Further, because this language is permissive rather than definitional, DrugLogic asserts, it does not impose any limitation on the scope of the claim. *Id*. at 11 (citing *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1304-05 (Fed. Cir. 2003); *Nomadix, Inc. v. Hewlett-Packard*, 2011 U.S. Dist. LEXIS 122823 at *12 (C.D. Cal. Oct. 24, 2011)).

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1   With respect to language in the specification discussing use of a web browser to access the

2   World Wide Web, *see, e.g.,* '091 patent, col. 5, ll. 64-64 & col. 10, ll. 36-39, this language does not

3   trump the clear meaning of the claim term, DrugLogic asserts. *Id*. (citing *Comark Communs. Inc. v.*

4   *Harris Corp*., 156 F.3d 1182, 1187 (Fed. Cir. 1998)). Moreover, DrugLogic asserts, the

5   specification discloses alternatives, stating "[t]he interface for the system could be the familiar

6   unmodified Web browser, a Web browser customized with special features, or a unique Web

7   application." *Id* (quoting '091 patent, col. 6, ll. 2-4).

8   Finally, DrugLogic argues that "Oracle's own marketing materials and user's manuals belie

9   their proposed construction" to the extent they recognize the Web is a "network of servers that

10   contain programs and files [in which] . . . many of the files contain hypertext links to other

11   documents available through the network." *Id*. & Ex. 4 (excerpt from Oracle's user's manual).

12   Oracle responds that there is no dispute as to the meaning of the term "remote user" and that

13   the only dispute between the parties is "whether accessing data 'through the World Wide Web'

14   includes a user accessing data located within that user's private network." Oracle Responsive Brief

15   at 19. According to Oracle, the term "through the World Wide Web," by its plain language,

16   "requires use of the world-wide system of Internet servers that make up the 'World Wide Web.'"

17   *Id*. (citing '091 patent, col. 5, ll. 56-60). DrugLogic's position, Oracle asserts, "flies in the face of

18   the claimed functionality of the '091 patent, and so must be rejected." *Id*.

19   Oracle argues that the '091 specification "touts the use of the World Wide Web . . . as a

20   prime innovation" of the '091 patent, citing the following passages of the '091 specification:

21   "Access to the present invention is provided by means of the Web." (col. 12, ll. 38-39); "[N]one of

22   [the prior art] references provides a web-based system and method for analyzing the risks of adverse

23   effects resulting from the use of a particular drug . . ." (col. 4, ll. 24-28); "The system of the present

24   invention is a web-based system . . ." (col. 4, ll. 41-42). *Id*. at 20. Oracle also cites the

25   specification's description of the Web as a "sophisticated worldwide network of computer systems

26   linked together by web pages." *Id*. (quoting '091 patent, col. 10, ll. 31-45). Oracle further points to

27   statements that "[a] user at an individual PC (i.e., workstation) that wishes to access the WWW

28   typically does so using a software application known as a web-browser" and that "[a] web browser

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makes a connection via the WWW to other computers known as web servers, and receives information that is displayed in the user's workstation." *Id.* (quoting '091 patent, col 10, ll. 36-39 & ll. 38-42).

Further, Oracle contends, the specification offers detailed reasons why the use of the Web is important to the effective analysis of the risks of adverse effects resulting from a drug. *Id.* (citing '091 patent, col. 6, ll. 42-46 ("the web-based analysis of adverse drug effects of the present invention permits multiple users to concurrently assess the hypotheses regarding the possible existence and causation of the adverse drug effects"); col. 6, ll. 47-51 ("[t]he web-based analysis of adverse drug effects of the present invention also permits users to assess hypotheses regarding the possible existence and causation of the adverse drug effects on a continuous, real-time basis, 24 hours a day, 7 days a week"); col. 6, ll. 52-54 ("[t]he web-based analysis of adverse drug effects of the present invention further permits users to access the application world-wide, without any geographic limitation"); col. 6, ll. 60-62 ("[t]he above-described geographic and coherent/consistent advantages permit greater cooperation among researchers, even if affiliated with different organizations"); col. 6, ll. 55-59 ("the web-based analysis of adverse drug effects of the present invention further permits the application to be run from a server and accessed by standard browsers, thus obviating the need for special software or downloads")). Oracle argues that these clauses *are* definitional, notwithstanding DrugLogic's assertions to the contrary. *Id.* 21. Thus, the statement that "the present invention" "obviate[s] the need for special software or downloads" "means that any sort of 'web-based analysis' that does require 'special software or downloads' is not the web-based analysis of the '091 patent." *Id.* (citing *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1304 (Fed. Cir. 2003)).

Oracle further contends that its proposed construction is consistent with technical dictionaries at the time of the filing of the '091 patent. *Id.* at 21. Oracle cites the 2001 edition of Newton's Telecom Dictionary, which defines the World Wide Web as "the universe of accessible information available on many computers spread through the world and attached to that gigantic computer network called the Internet." *Id.* (citing Von Der Ahe Decl., Ex. O).

1   Oracle argues that DrugLogic's reliance on *Phillips* is misplaced because in that case, the

2 court refused to import a limitation from the specification because the limitation was already

3 included in the patent's other claims. *Id.* (citing 415 F.3ds at 1327). That is not the situation here,

4 Oracle contends, because only claims 1 and 8 discuss the World Wide Web. *Id.* Oracle also rejects

5 DrugLogic's reliance on *Nomadix*. *Id.* According to Oracle, in that case the court refused to import

6 a limitation from a preferred embodiment. *Id.* (citing 2011 U.S. Dist. LEXIS 122823, at * 12 (C.D.

7 Cal. Oct. 24, 2011)). Here, in contrast, "Oracle is not drawing its proposed claim language from a

8 preferred embodiment but directly from the '091 patent's description of the 'present invention.'" *Id.*

9 *(citing Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368-1370 (Fed. Cir. 2003)).

10   In its response, DrugLogic argues that the exclusion of private networks under Oracle's

11 proposed construction contradicts the specification, which describes a private network as a preferred

12 embodiment. DrugLogic Reply Brief ('091 patent) at 3-4 (citing '091 patent, col. 11, ll. 45-51).

13 Such a construction is ordinarily incorrect, DrugLogic contends. *Id.* at 4 (citing *Verizon Servs.*

14 *Corp. v. Vonage Holdings, Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007)). DrugLogic challenges

15 Oracle's reliance on statements in the specification providing "that the web-based analysis aspect of

16 'the present invention' *permits* certain advantages." *Id.* (citing Oracle Responsive Brief ('091

17 patent) at 24; '091 patent, col. 6, ll. 42-63). According to DrugLogic, Oracle provides no support for

18 its contention that private networks cannot offer these advantages and in any event, the word

19 "permit" in the specification is not a term of exclusion. *Id.* (citing *SunRace Roots Enterprises Co.,*

20 *Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1304 (Fed. Cir. 2003)). DrugLogic argues that the statements

21 cited by Oracle merely describe the advantages of the invention and therefore are not limiting. *Id.*

22 (citing *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319 (Fed. Cir. 2006); *Brookhill-Wilk 1, LLC v.*

23 *Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003); *Flexhead Indus. Inc. v. Easyflex, Inc.*,

24 2008 U.S. Dist. LEXIS 91848 * 9-10 (D. Mass. Nov. 3, 2008)).

25   Finally, as to Oracle's position that the claims do not cover use of special software and

26 downloads, DrugLogic argues again that this is merely one *advantage* of the claims; the fact that it is

27 not required, DrugLogic asserts, is illustrated by the statement in the specification describing

28 implementation of the invention with a "Web browser with customized features" or a "unique web

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1 application." *Id*. According to DrugLogic, customized features or unique web applications are

2 "often installed using special software or downloads." *Id*. at 5.

3   **ii.**   **Analysis**

4   The primary dispute with respect to this claim term is whether the words "through the World

5 Wide Web" permit a construction that includes a user accessing data that is located solely within a

6 private network, or intranet. The parties also dispute whether the term should be construed to

7 include a limitation requiring that the user must be able to access previously stored information

8 "using a standard Web browser, without using special software or downloads." As to the first

9 question, the Court concludes that this claim term requires use of one or more Internet servers to

10 access data. The ability to practice the invention using a standard web browser, however, is simply

11 an advantage of the invention that is not properly included in the Court's construction of this claim

12 term.

13   The Court starts with the words of the claim, which expressly state that the claimed invention

14 permits "access . . . through the World Wide Web." '091 Patent, claim 1. Any question as to the

15 meaning of these words is dispelled by the specification, which defines the World Wide Web as "a

16 system of Internet servers that support specially formatted documents." '091 patent, col. 5, ll. 56-57.

17 Further, the specification repeatedly describes the invention as being "web-based," pointing to this

18 aspect of the invention as a key feature distinguishing it from the prior art. *See* '091 patent, col. 12,

19 ll. 38-39 ("Access to the present invention is provided by means of the Web."); col. 4, ll. 24-28

20 ("[N]one of [the prior art] references provides a web-based system and method for analyzing the

21 risks of adverse effects resulting from the use of a particular drug . . ."); col. 4, ll. 41-42 ("The

22 system of the present invention is a web-based system . . ."). In touting this advantage of the

23 invention over the prior art, the specification makes clear that the words "through the World Wide

24 Web" require that access must be through one or more Internet servers and that the invention does

25 not include embodiments that utilize only a private intranet. *See Tronzo v. Biomet*, 156 F.3d 1154,

26 1159 (Fed. Cir. 1998).

27   The language in the specification cited by DrugLogic referring to the use of the invention

28 within a single company or organization, *see e.g.,* '091 patent, col. 10, ll. 24-29, col. 11, ll. 45-51,

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1 col. 13, ll. 10-15, does not persuade the Court that "access . . .through the World Wide Web"

2 includes an embodiment using only an intranet where there is no access to an Internet server.

3 Rather, the specification explains that an intranet can be used *together with* a Web server. *See* '091

4 patent, col. 11, l. 56 - col. 12, l. 12. Nothing in the specification suggests that use of an intranet

5 alone satisfies this claim term.

6   Next, the Court addresses Oracle's proposed limitation, "using a standard Web browser,

7 without using special software." This language tracks the disclosure in the specification stating that

8 "the web-based analysis of adverse drug effects of the present invention further permits the

9 application to be run from a server and accessed by standard browsers, thus obviating the need for

10 special software or downloads." '091 patent, col. 6, ll. 55-59. The Court looks to the cases cited by

11 the parties for guidance on the question of whether the ability to use a standard Web browser

12 without special software is a limitation or whether it merely describes an advantage that is associated

13 with a preferred embodiment of the invention.

14   In *SunRace Roots*, cited by both parties, the Federal Circuit addressed whether the claim term

15 "shift actuator" should be construed more restrictively than its ordinary meaning. 336 F.3d at 1304.

16 The district court had limited the meaning of the claim term to a device containing the cam structure

17 of the preferred embodiment, relying on language in the specification 1) describing "one of the

18 objects of the invention;" 2) describing an "important part of the invention;" 3) stating that "[e]ach

19 handgrip shift actuator contains a generally cylindrical cam member having a generally helical

20 operating face configured with a plurality of spaced detents or valleys with a cam peak or lobe

21 between each pair of adjacent detents;" and 4) stating that "[a] rotary cam member 74 having a

22 generally helical operating face is the heart of the rear handgrip shift actuator." *Id*. The Federal

23 Circuit concluded that these statements did not "sufficiently evidence an intention to depart from the

24 ordinary meaning of "'shift actuator.'" *Id*.

25   With respect to the first two passages, the Federal Circuit explained, these statements

26 "simply detail[ed] some of the goals of the invention that are achieved by some of the apparatus

27 claims." *Id*. These did not limit the meaning of the claim term, however, because the specification

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1   also recited other goals that did not address the use of cams. *Id*. The third and fourth statements

2   were "more problematic" but the Federal Circuit found that they "still [did] not define the term shift

3   actuator" and did not constitute expressions of "clear exclusion" but instead was "more properly

4   characterized as descriptive of the preferred embodiments." *Id*. While acknowledging that a claim

5   term can be given a narrow construction based on a preferred embodiment where the patent has

6   described the preferred embodiment as the invention itself, the court found that that approach did not

7   apply, citing the fact that an original claim recited a shift actuator generally whereas another called

8   for a *handgrip* shift actuator. *Id*. The court concluded that patentees had "contemplated a broad

9   class of shift actuators containing a subcategoryof handgrip shift actuators, which in turn contained a

10   subcategory of handgrip shift actuators employing a cam mechanism." *Id*. at 1304-1305.

11   In *Nomadix*, cited by DrugLogic, the court addressed whether the term "management

12   system" should be limited to a system that was "connected to the gateway device by a direct link."

13   2011 U.S. Dist. LEXIS, at * 11-12 (C.D. Cal. 2011). The party seeking the limitation quoted the

14   following statements in the specification: the "network gateway devices communicat[e] with

15   management systems;" that "according to one aspect of the invention, the gateway device is in direct

16   communication with the management system;" and that "[t]ypically the gateway device [] is

17   connected . . .to the management system." *Id*. at *12. The court concluded that "[n]one of [this]

18   language require[d] that the management system must be physically connected to the gateway

19   device." *Id*. Instead, the court concluded that the term needed no construction. *Id*.

20   In *Alloc, Inc. v. Valinge Aluminium, AB*, cited by Oracle, the Federal Circuit held that a

21   patent was directed to flooring systems and methods of joining those flooring systems with play

22   between the locking groove and the locking element, even though none of the claim terms included

23   the word "play." 342 F.3d at 1370. In reaching this conclusion, the court relied on the following

24   description of the invention, under the heading of "Technical Problems and Objects of the

25   Invention:"

26   provid[ing] a system for making a joint along adjacent joint edges of two building panels,
            especially floor panels . . . said system being characterized in that . . . the panels, when joined
27   together, can occupy a relative position in said second direction where a play exists between

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1   the locking groove and a locking surface on the locking element that is facing the joint edges
     and is operative in said second mechanical connection.

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3   *Id*. at 1368-1369. The court went on to point to language stating that the "objects of the invention

4   are achieved by means of a panel-joining system having the features recited in the appended claims."

5   *Id*. at 1369. The court also relied on language in the specification describing the various advantages

6   a system with play permitted, such as "displacement" and "disassembly and reassembly of a floor

7   previously laid without causing damage to the panels." *Id*. Finally, the court pointed to language in

8   the specification criticizing prior art floor systems that did not have play. *Id*. at 1369-1370.

9   The Court concludes that the language in the '091 patent referring to the ability to use the

10   invention without special software, like the language in *SunRace Roots* and *Nomadix*, is not

11   definitional language that constitutes an expression of clear exclusion. Rather, it describes a

12   preferred embodiment.

13   The Court construes the term "permitting at least one remote user to access such data through

14   the World Wide Web"as follows: "permitting a user at one computer to access information reflecting

15   occurrences of adverse events on a different computer or server, through one or more Internet

16   servers."

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3.   Disputed Claim Terms From Dependent Claims 4-6 and 11-13

a.   "a comparator to measure the reactions to the at least one [drug/substance][9] of interest against a user-defined backdrop" (Claims 4 and 11) and "comparator" (Claims 6 and 13)

DrugLogic's Proposed Construction	Oracle's Proposed Construction
"an application that compares the reactions to a particular drug of two user-defined data sets"	"an analysis tool that compares the potential adverse effects of a drug in the premarket environment to the actual adverse effects of that drug in the post-market environment"

i.   The Parties' Positions

DrugLogic contends that its proposed construction is consistent with the language of claims 4 and 11. DrugLogic Opening Brief ('091 patent) at 20. Claims 4 and 11 provide, in part, as follows:

> The computer-implemented method for assessing and analyzing the risks of adverse effects resulting from the use of at least one [drug/substance] of interest . . .wherein the at least one data mining engine is a comparator to measure the reactions to the at least one drug of interest against a user-defined backdrop.

'091 patent, claims 4 & 11. According to DrugLogic, this language "defines a comparator as an application that compares the reactions to a particular drug of two user-defined data-sets." DrugLogic Opening Brief ('091 patent) at 20. Further, it contends, the specification confirms this construction, stating that "[t]he comparator can compare any two sets of cases for any two dimensions." *Id* (quoting '091 patent, col. 24, ll. 30-31). DrugLogic acknowledges that the specification describes a comparator that allows a user to compare reactions reported in pre-market data to reactions reported in post-market data, but argues that this is a preferred embodiment. *Id*. at 20-21 (citing '091 patent, col. 24, ll. 1-22 (describing comparator in the "preferred offering" as comparing pre- and post-market data); col. 15, ll. 29-35 (stating that "an additional preferred aspect of this home page is the comparator . . . [which] compares potential and adverse effects of drugs in the pre- and post- market environments")).

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[9]Claim 4 uses "drug" throughout while claim 11 uses "substance" throughout.

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1   Oracle argues that this claim term is limited to a comparator that compares pre-market

2 reactions to post-market reactions, asserting that every reference to the comparator is definitional,

3 describing the "comparator engine of the present invention" and therefore is not simply describing

4 preferred embodiments. Oracle Responsive Brief ('091 patent) at 22-23. In particular, Oracle points

5 to the following two passages of the specification:

6   The comparator engine of the present invention is a differencing engine that is applied to
          measuring one drug's reactions, both pre-and post- market.
7

8 *Id.* (quoting citing '091 patent, col. 24, ll. 23-25).

9   The comparator compares potential and adverse effects of drugs in the pre- and post-market
          environments.
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11 *Id*. at 22-23 (quoting '091 patent, , col. 15, ll. 33-35).

12   Oracle concedes that a comparator that allows for a comparison of pre- and post- market

13 reactions is described in the patent as part of the preferred embodiment, but contends that this is also

14 an essential feature of the "present invention." *Id*. n. 8 (citing DrugLogic Opening Brief ('091

15 Patent) at 20 (quoting '091 patent, col. 24, ll. 1-22, col. 15, ll. 29-35)). Oracle also points to Figures

16 2 in support of its position, showing the three data mining engines of the '091 patent as the

17 "Proportional" engine, the "Correlator" engine and the "pre-post" engine. *Id*. at 23. Based on a

18 passage in the specification referring to the three data-mining engines of the '091 patent as the

19 "Proportional" Engine, the "Comparator" engine and the "Correlator" engine, Oracle contends that

20 the term "comparator" in the '091 patent is used interchangeably with "pre-post market" engine,

21 showing that this is an essential element of the comparator. *Id*. Oracle also points to Figure 20,

22 which is described as "an illustration of a comparator screen of the present invention." '091 patent,

23 col. 8, ll. 32-33. The screen in that figure includes "Pre-Post Market" in the heading.

24   In its reply, DrugLogic reiterates its position that the language of the specification makes

25 clear that the comparator allows the comparison of pre- and post market reactions in preferred

26 embodiments but that the comparator can be used to compare other user-defined data sets as well.

27 DrugLogic's Reply Brief ('091 patent) at 14-15.

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ii.   Analysis

The Court starts its analysis with the plain language of the claims. Claims 4 and 11 require only that the comparator allow for the comparison of reactions as to two data sets or criteria. They do not require that the comparisons must be *between* pre-market data and post-market data. Admittedly, the specification states that the "comparator compares potential and actual adverse effects of drugs in the pre- and post- market environment." '091 patent, col. 15, 33-35.   As a matter of basic grammar, however, this does not require that pre-market data must be compared to post-market data. Rather, it simply means that the comparison can be conducted as to both pre- and post-market data.   Similarly, the passage stating that "[t]he comparator engine of the present invention is a differencing engine that is applied to measuring one drug's reactions, both pre- and post-market," '091 patent, col. 24, ll. 23-25, does not state that pre- market data must be compared to post-market data. Further, the Court concludes that Figures 2 and 20, which appear to depict a comparator that compares pre-market data to post-market data, are preferred embodiments and do not support importing this limitation into the Court's construction of this claim term. Accordingly, the Court adopts DrugLogic's proposed construction, construing the terms "a comparator to measure the reactions to the at least one [drug/substance] of interest against a user-defined backdrop" and "comparator" as "an application that compares the reactions to a particular drug of two user-defined data sets."

b.   **"a correlator to look for correlated signal characteristics among drug, reaction, and demographic information" (Claims 5, 12) and "correlator" (Claims 6, 13)**

Term	DrugLogic's Proposed Construction	Oracle's Proposed Construction
"a correlator to look for correlated signal characteristics among drug, reaction, and demographic information"	"an analysis tool that measures the degree of association among pairs of certain drug, reaction, and demographic values"	**Initial**: "an analysis tool that uses an algorithm to measure the degree of correlation between drug, reaction, and demographic information concurrently" **Modified**: "an analysis tool that concurrently measures the degree of correlation among multiple pairs of drug, reaction, and demographic information"
"correlator"	"an analysis tool that measures the degree of association among pairs of values"	Same as above

i.   **Parties' Positions**

DrugLogic contends that its proposed construction of these claim terms is true to the claim language. DrugLogic Opening Brief ('091 patent) at 21. In particular, claims 5 and 12 provide for a "correlator to look for correlated signal characteristics among drug, reaction and demographic information." *Id.* (quoting '091 patent, claims 5 and 12). Oracle's proposed construction is not helpful, DrugLogic asserts, to the extent it "essentially provides that a correlator measures correlation." *Id.* Instead, DrugLogic points to the specification, which it contends provides a "better definition," stating: "[t]he correlator looks for the association of characteristics in literally millions of pieces of drug/ reaction/ demographic information concurrently." *Id.* at 21 (quoting '091 patent, col. 20, ll. 65-67). According to DrugLogic, Oracle's proposed construction is inconsistent with this language in the specification, with the word "concurrently" implying that drug, reaction and demographic information all must be measured for correlation at the same time. *Id.* DrugLogic argues that in fact, only two data elements need be measured together, quoting the following passage

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1   in the specification:

2   Too often in risk assessment, important correlations are hidden by surrounding background
        'noise' that obscures connections among data elements. Using a multidimensional vector
3   analysis, the correlator measures the degree of association among pairs of values (for
        example, a drug and a reaction, an age and an outcome, etc.).
4

5   *Id*. at 22 (quoting '091 patent, col. 21, ll. 1-7).

6   In response, Oracle argues that its proposed construction is correct because "[a] 'correlator'

7   necessarily measures the degree of 'correlation' between the variables," implicitly rejecting

8   DrugLogic's use of the word "association" in its proposed construction. Oracle's Responsive Brief

9   ('091 patent) at 24. More importantly, Oracle asserts, DrugLogic's proposed construction does not

10 reflect the requirement that the correlator use "a multidimensional vector analysis." *Id*. (quoting

11 '091 patent, col. 21, ll. 3-6 ("Using a multidimensional vector analysis, the correlator measures the

12 degree of association among pairs of values (for example, a drug and a reaction, an age and an

13 outcome, etc.)."). That requirement is captured in Oracle's proposed construction, it contends, by the

14 word "concurrently," which is consistent with the language in the specification describing the

15 correlator as "look[ing] for the association of characteristics in literally millions of pieces of

16 drug/reaction/demographic information concurrently." *Id*. (quoting '091 patent, col. 20, ll. 65-67).

17 Oracle also points to Figure 13, which demonstrates that the correlator "simultaneously runs across

18 multiple dimensions (including sex, target drug, reaction and outcome), in order to achieve its

19 results." *Id*. at 24-25. Oracle concedes that the correlator compares pairs of values, however, and

20 therefore modifies its proposed construction to the following: "an analysis tool that concurrently

21 measures the degree of correlation among multiple pairs of drug, reaction, and demographic

22 information." *Id*. at 25.

23   In its reply brief, DrugLogic rejects Oracle's modified proposed construction. DrugLogic's

24 Reply Brief ('091 patent) at 15-16. First, it reiterates its position that Oracle's proposed construction

25 will not be helpful to the jury to the extent it defines a correlator as something that measures

26 correlations. *Id*. at 15. Second, it contends that Oracle's modified construction does not remedy the

27 problem DrugLogic identified in its opening brief, namely, suggesting that all three values – drug,

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1 reaction and demographic information – must be measured for correlation concurrently.[10] *Id.*

2   **ii.**   **Analysis**

3   The disputes relating to this claim term do not appear to be based on any fundamental

4 disagreements about the function of the correlator in the '091 patent or how that function is

5 performed. Oracle agrees that the correlator measures correlations between *pairs* of values, while

6 DrugLogic does not dispute that the means of performing this operation is by multidimensional

7 vector analysis. Rather, the parties' disagreements turn on whose proposed construction best

8 conveys to the jury what these terms mean. The Court adopts a modified construction that adopts

9 some elements of the constructions proposed by the parties.

10   First, as to whether the correlator should be construed as something that measures the degree

11 of "association" as opposed to the degree of "correlation" between pairs of values, the Court finds

12 no difference in meaning between the two. Indeed, the patentee appears to have used them

13 interchangeably. *See* '091 patent, col. 21, ll. 4-5. Therefore, the Court adopts in its construction the

14 word "association" rather than "correlation" as it may be helpful for the jury to be offered a

15 synonym for "correlation."

16   Second, the Court agrees with Oracle that DrugLogic's proposed construction does not

17 convey the multidimensional aspect of the analysis conducted by the correlator. On the other hand,

18 Oracle's proposed construction is, arguably, somewhat awkward and possibly confusing. Therefore,

19 the Court construes "a correlator to look for correlated signal characteristics among drug, reaction,

20 and demographic information" and "correlator"as follows: "an analysis tool that concurrently

21 searches drug, reaction and demographic information to measure the degree of association among

22 pairs of certain drug, reaction, and demographic values."

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27   [10]The Court notes that neither side addresses the stand-along term "correlator," for which
DrugLogic offers a broader construction; Oracle offers the same proposed construction for both claim

28 terms.

B.   The '221 Claim Terms

1.   "Clinical Terms" (Claim 1)

Oracle's Proposed Construction	DrugLogic's Proposed Construction
No construction required or "Terms pertaining to the study or observation of medical patients, such as terms in a medical dictionary"	"Terms pertaining to the study or observation of medical patients"

a.   Parties' Positions

Oracle contends that "clinical terms" is a commonly understood phrase with no special

meaning in the context of the '221 patent and therefore, that it requires no construction. Oracle's

Opening Brief Regarding Construction of Disputed Terms in the '221 patent ("Oracle's Opening

Brief ('221 patent)") at 6. In the alternative, if the Court concludes that construction is necessary,

Oracle argues that it should adopt Oracle's proposed construction, which differs from DrugLogic's

construction only to the extent it includes the exemplary phrase "such as terms in a medical

dictionary." *Id*. at 7. This phrase should be included, Oracle asserts, because "[a]t the heart of this

dispute is whether terms in a medical dictionary are 'clinical terms'" within the meaning of the '221

patent. *Id*.

Oracle points to the specification in support of its contention that "clinical terms" includes

terms from a medical dictionary. *Id*. In particular, the specification describes a preferred

embodiment in which "[t]he clinical terms are initially transmitted to the thesaurus database 18 from

an external media source, such as a CD-ROM." *Id*. (quoting '221 patent, col. 3, ll. 40- 43). The

"external media source," in turn, is described as follows:

> Typically, external media sources are purchased in the form of a dictionary on a CD-ROM
> from an external vendor. Common vendor-supplied dictionaries include WHO-Drug (World
> Health Organization Drug Dictionary) by the World Health Organization, COSTART
> (Coding Symbols for a Thesaurus of Adverse Reaction Terms) by the Drug Information
> Association, and CPT (Current Procedural Terminology) by the American Medical
> Association. Other vendors and dictionaries are common and known in the industry.

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1   '221 patent, col. 4, ll. 2-11. In addition, Oracle points to the description of Figure 7, referring to

2   terms from vendor-supplied dictionaries as "clinical terms." Oracle Opening Brief ('221 patent) at 7

3   (quoting '221 patent, col. 7, ll. 9-11) ("Referring to Fig. 7, there are several types of terms which

4   may be stored in the thesaurus database as clinical terms"). Further, Figure 7 shows that the medical

5   dictionary supplied terms are included in the broader category of "clinical terms." *Id.* at 8 (citing

6   '221 patent, Fig. 7). DrugLogic's proposed construction is improper, Oracle asserts, because it

7   would exclude terms derived from medical dictionaries, thereby excluding the preferred embodiment

8   shown in Figure 7. *Id.* (citing *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir.

9   1996)).

10   In its responsive claim construction brief, DrugLogic states that it would agree that "the term

11   'clinical term' alone does not require construction" if it were not for the exemplary language Oracle

12   has requested as part of its construction ("such as terms in a medical dictionary"). DrugLogic, Inc.'s

13   Corrected Responsive Claim Construction Brief on United States Patent No. 6,684,221

14   ("DrugLogic's Responsive Brief ('221 patent)" at 12 n. 10. DrugLogic concedes that the ordinary

15   meaning of "clinical terms," outside the context of the '221 patent, would include terms from a

16   medical dictionary. *Id.* at 11 ("terms in a prior art medical dictionary may be 'clinical' in the sense

17   that they may relate to the treatment of a patient"). It also does not dispute that the specification

18   describes a preferred embodiment in which "clinical terms" are drawn from a medical dictionary.

19   *Id.* at 11-16. It argues, however, that the claims, read as a whole, support a more limited

20   construction of the phrase "clinical terms," especially in light of the prosecution history. *Id.*

21   DrugLogic points out that claim 1 recites, in part, "[a] method for storing a thesaurus of

22   clinical terms comprising: defining a plurality of *clinical terms for use in conjunction with a clinical*

23   *study . . . ." Id.* at 9 (quoting '221 patent, col. 9, ll. 16-17) (emphasis in DrugLogic's brief). The

24   language in italics, DrugLogic contends, makes clear that "clinical terms" recited in the claims "are

25   *not just any clinical terms,* for example clinical terms that might be found in a medical dictionary."

26   *Id.* at 10. Rather, they must be related to a particular clinical study. *Id.* This is because "the entire

27   purpose of the invention is to build a thesaurus of clinical terms that are not already contained in an

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existing medical/clinical thesaurus," DrugLogic asserts. *Id*. at 11. In other words, DrugLogic

contends, "[t]he invention allows a user to add new clinical terms from a clinical study to an existing

medical thesaurus, to structure the new terms in accordance with a hierarchy, and to define

relationships between the added terms and previously loaded terms in the database." *Id*. at 5. To the

extent clinical terms contained in a medical dictionary are not necessarily related in any way to a

clinical study, DrugLogic asserts, such terms do not fall within the scope of the claims. *Id*.

DrugLogic concedes that the specification describes a preferred embodiment in which terms from a

medical dictionary are described as "clinical terms." *Id*. at 10-11. It argues, however, that the

language of the claim must "prevail over inconsistent language in the specification." *Id*. (citing

Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1308 (Fed. Cir. 2000)).

Similarly, DrugLogic argues that the doctrine of prosecution history disclaimer limits the

phrase "clinical terms" to exclude terms from medical dictionaries. *Id*. at 12-16. In particular,

DrugLogic argues that the applicant amended all of the claims to overcome a final rejection "to

specify, with more particularity, that the invention relates to a thesaurus of clinical terms *for use in*

conjunction with a clinical study." *Id*. at 13 (emphasis in DrugLogic's brief). DrugLogic points to

the following arguments made by the applicant in support of allowance of the amended claims:

> … Gusack was cited by the Office to show the hierarchy of relations, but Gusack does not relate to the claimed hierarchy of relations *used in conjunction with a clinical study*. . . . There is nothing in Gusack or in any other cited reference that suggests that clinical terms should be stored in a thesaurus of terms according to a hierarchy of relations for use in conjunction with a clinical study.
>
> In fact, none of the cited references relate to clinical studies. Further, the references do not address the issues associated with clinical studies, such as the inconsistencies in terminology in the medical field. With the claimed invention, however, clinical terms for a clinical study are stored according to a hierarchy of relations . . .

Id., Ex. 9, p. 8 (underlining in original; bold-italics added by DrugLogic). Based on this language,

DrugLogic contends that the "applicant unequivocally disclaimed a thesaurus of clinical terms

wherein the terms are compiled from sources other than clinical studies, such as existing medical

dictionaries." *Id*. (citing *Seachange Int'l, Inc. v. C-COR Inc*., 413 F.3d 1361, 1375 (Fed. Cir. 2005);

Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed. Cir. 2002); *Andersen Corp. v. Fiber*

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1 *Composites, LLC,* 474 F.3d 1361, 1368-69 (Fed. Cir. 2007)). Accordingly, DrugLogic argues, the

2 phrase "clinical terms" cannot be construed to encompass clinical terms from vendor supplied

3 medical dictionaries, even though the specification of the '221 patent describes an embodiment in

4 which "clinical terms" are obtained from such external sources. *Id*. at 15.

5 　　　　DrugLogic further contends that Oracle's proposed construction would render the patent

6 invalid because claim 1 would claim an invention that was essentially the same as the existing prior

7 art medical dictionaries. *Id*. at 16. Because the Court should construe the term to preserve its

8 validity, DrugLogic asserts, Oracle's proposed construction should be rejected. *Id*. (citing *Rhine v.*

9 *Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999)).

10 　　　　In its reply brief, Oracle argues that DrugLogic's reliance on the doctrine of prosecution

11 disclaimer is misplaced and that DrugLogic has mischaracterized the prosecution history. Oracle's

12 Reply Brief Regarding the Construction of Disputed Terms in the '221 patent ("Oracle Reply Brief

13 ('221 patent)") at 3. According to Oracle, DrugLogic has incorrectly suggested that the PTO

14 rejected the claims, as originally drafted, because existing medical dictionaries rendered them

15 obvious, requiring the applicant to narrow the claims to exclude terms from medical dictionaries. *Id*.

16 In fact, Oracle contends, the prior art cited by the Examiner as grounds for rejection did not include

17 *any* medical dictionaries. *Id*. at 3-4. Consequently, the applicant's amendments did not address

18 whether "clinical terms" could be drawn from preexisting medical dictionaries. *Id*. at 5. Under

19 these circumstances, there was no clear disclaimer of claim scope, Oracle contends. *Id*. at 8-9.

20 　　　　Furthermore, Oracle argues, the language of the claims does not support DrugLogic's

21 position. *Id*. at 7. According to Oracle, DrugLogic wrongly equates the phrase "for use in" with the

22 phrase "to derive from." *Id*. (quoting DrugLogic's assertion that "Oracle's proposed construction of

23 'clinical terms' including the exemplary phrase, 'such as terms in a medical dictionary,' is

24 inappropriate as the applicant unequivocally disclaimed an invention including clinical terms

25 **derived from** sources other than clinical studies, such as existing medical dictionaries, during

26 prosecution" and that "[t]he applicant unequivocally disclaimed an invention including clinical

27 terms *derived from* sources other than clinical studies, such as existing medical dictionaries"). *Id*. at

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1   7. Oracle argues, "the basic invention of the '221 patent is a method of creating a thesaurus of

2   clinical terms by gathering those terms from various sources, including standardized medical

3   dictionaries, company terms, and elsewhere, and building them into one hierarchical, relational

4   thesaurus of terms." *Id*. According to Oracle, "[t]hat the stated *purpose* of this thesaurus of clinical

5   terms is 'for use in conjunction with a clinical study' has nothing logically to do with the potential

6   *sources* of the clinical terms." *Id*.

7   Finally, Oracle rejects DrugLogic's contention that Oracle's proposed construction would

8   render the claims invalid over standardized medical dictionaries. *Id*. at 9. Oracle argues that

9   DrugLogic has offered no charts or details about any prior art showing that the claims would be

10   invalid and that in fact, standard medical dictionaries do not teach every aspect of the '221

11   invention. *Id*. at 9-10. Oracle also argues that the argument is premature to the extent it goes to

12   validity and that in any event, claims should be construed to preserve validity only "if possible." *Id*.

13   **b.   Analysis**

14   In "rare case[s]" in which the language of an amended claim is unambiguous and there was a

15   clear disclaimer of claim scope during the prosecution of a patent, a construction that excludes a

16   preferred embodiment may be "compelled." *Elekta Instrument S.A. v. O.U.R. Scientific Intern*.,

17   214 F.3d 1302, 1308 (Fed. Cir. 2000). This is not such a case. Contrary to DrugLogic's assertions,

18   the language of the claims does not clearly support the exclusion of clinical terms from medical

19   dictionaries and thesauruses; nor does the prosecution history show a clear disclaimer of

20   embodiments in which the claim term "clinical terms" encompasses terms derived from existing

21   medical dictionaries or thesauruses. Therefore, the Court adopts Oracle's proposed construction.[11]

22   As to the claim language, DrugLogic's position fails as a matter of grammar: the requirement

23   that clinical terms must be "for use in conjunction with a clinical study" says nothing that suggests

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26   [11]The Court concludes that construction of this term is appropriate because failure to construe "clinical terms" would leave unresolved a key dispute between the parties. See *O2 Micro Intern. Ltd.*

27   *v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008)(holding that even if a claim term has a plain and ordinary meaning, the court should construe the term if construction is required to resolve a dispute about the scope of the asserted claims, which is a question of law to be

28   decided by the Court).

1   those terms must be *derived from* a clinical study, much less a particular clinical study, as

2   DrugLogic contends. Nor does the specification support DrugLogic's contention that the "entire

3   purpose of the invention is to build a thesaurus of clinical terms that are not already contained in an

4   existing medical/clinical thesaurus." To the contrary, the specification describes a preferred

5   embodiment in which "clinical terms" expressly include terms from an existing dictionary or

6   thesaurus, as DrugLogic concedes.

7   Further, the prosecution history does not support DrugLogic's position that the applicant

8   limited the scope of the invention to exclude clinical terms from a medical dictionary. Rather, the

9   applicant argued that the invention claimed in claim 1 (and other claims with similar language) was

10 patentable over the prior art referenced by the Examiner because: 1) Coulter, while reciting an

11 indexing system that can provide a thesaurus table with unique terms from text documents and stores

12 links between the terms and their respective text documents, "does not suggest that the terms should

13 be stored according to a hierarchy of relations;" 2) Gusack "is directed to defining data clusters such

14 that links are not made directly between any two records but, instead, are made between groups of

15 records stored in a plurality of tables in a date set" and therefore, "nothing in Gusack . . .suggests

16 that clinical terms should be stored in a <u>thesaurus of terms</u> according to a <u>hierarchy of relations</u> for

17 use in conjunction with a clinical study;" and 3) "none of the cited references relate to clinical

18 studies" and "the references do not address the issues associated with clinical studies, such as the

19 inconsistencies in terminology in the medical field" – difficulties that are addressed in the '221

20 invention by use of a "hierarchy of relations [that] allows the clinical terms to be organized

21 according to degrees of more general and more specific terms." Von Der Ahe Reply Decl., Ex. I

22 (June 9, 2003 Applicants Response) at 8 (emphasis in original).[12]

23   In short, none of the arguments in support of allowance even addressed the question of

24 whether "clinical terms" included terms in existing medical dictionaries. The only argument that

25 comes close to addressing this issue is the argument that the prior art was not related to clinical

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27   [12]In the Reasons for Allowance, the Examine stated that these arguments were persuasive. Von

28 Der Ahe Decl., Ex. J at 2-3.

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studies at all, and therefore did not address the problems that the '221 invention was intended to address. As discussed above, however, requiring that the clinical terms be "for use in conjunction with a clinical study" is not the same as requiring that they be derived exclusively from such a study, to the exclusion of terms contained in existing medical dictionaries. Certainly, these arguments do not amount to an "unequivocal"disavowal of claim scope with respect to the term "clinical terms."

The Court also does not find persuasive DrugLogic's conclusory statement that Oracle's proposed construction would render the '221 patent invalid. Assuming it is appropriate to consider at the claim construction phase of the case whether a particular construction would render a patent invalid, DrugLogic has not offered sufficient evidence to show that any particular prior art reference would anticipate or render the '221 patent obvious under Oracle's proposed construction of "clinical terms."

The Court therefore construes "clinical terms" as follows: "terms pertaining to the study or observation of medical patients, such as terms in a medical dictionary."

2. "defining a plurality of clinical terms for use in conjunction with a clinical study" (Claim 1)

Oracle's Proposed Construction	DrugLogic's Proposed Construction
No construction required or "choosing a plurality of terms pertaining to the study or observation of medical patients for use in conjunction with a clinical study"	"developing a list of terms pertaining to the study or observation of medical patients used in connection with a particular clinical study"

a. Parties' Positions

Oracle contends that this claim term requires no construction because it is "nontechnical . . . and understandable to anyone." Oracle's Opening Brief ('221 patent) at 9. If the Court decides that construction is necessary, Oracle asserts that its proposed construction is most faithful to the plain and ordinary meaning of the term and the language of the patent. *Id*. Oracle highlights the use of the word "choosing" in its proposed construction, arguing that this is consistent with the teaching of the patent that clinical terms can be chosen in a variety of ways, including choosing them from a

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1   standard medical dictionary, using terms customized for a particular study ("domain terms") or using

2   terms that are in use with a user's company. *Id*. (citing '221 patent, col. 6, ll. 9-24). In particular,

3   the specification describes a preferred embodiment depicted in Fig.7 as follows:

> Referring to Fig. 7, there are several types of items which may be stored in the thesaurus
> database 18 as clinical terms 400. External terms 402 are loaded from vendor supplied
> dictionaries, typically from a CD-ROM, and loaded at one time. Company terms 402 are
> those specific to a particular company or enterprise, and are added to the thesaurus database
> 18 as needed to support the classification processing. Domain terms 404 are attributed to a
> particular study, and contain unpublished terms specific to the study.

8   '221 patent, col 7, ll. 9-18.

9   Oracle further asserts that the words of the claims support its proposed construction. Oracle

10   Opening Brief ('221 patent) at 9-10. Specifically, Oracle points to dependent claim 43, which

11   recites "[t]he system of claim 42 wherein the external media source is a medical dictionary." *Id*.

12   According to Oracle, the "external media source" in claims 14, 16 and 17 is where the clinical terms

13   are obtained and defined. *Id*. at 10.

14   Oracle asserts that DrugLogic's proposed construction is wrong for several reasons. *Id*.

15   First, the word "developing" in its proposed construction, in combination with the words "used in

16   connection with a particular clinical study," limits the claim term – as well as the phrase that

17   follows, "storing the plurality clinical terms in a memory according to a hierarchy of relations" – to

18   customized clinical terms created by the user, thereby excluding the preferred embodiment. *Id*.

19   (citing *Vitronics*, 90 F.3d at 1583).

20   Second, Oracle contends that DrugLogic's proposed construction is inconsistent with the

21   intrinsic evidence to the extent it limits clinical terms to those associated with a "particular study"

22   because the specification only refers to a "particular" study when it is describing domain terms. *Id*.

23   (citing '221 patent, col. 7, ll. 16-17, col. 5, ll. 57-58). The words "clinical terms" in this claim term

24   have a broader meaning, Oracle asserts, encompassing terms from medical dictionaries, company

25   terms and domain terms. *Id*.

26   Third, Oracle argues that DrugLogic's proposed construction is incorrect because when the

27   inventor intended to confine the claims to a particular study, he knew how to do so. *Id*. Oracle

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1   points out that claim 38, which depends from claim 22, is "addressed to 'a system for accessing a

2   thesaurus of clinical terms used in conjunction with a clinical study' . . . 'wherein the match terms

3   include common global terms and *domain* terms corresponding to *a particular study.*'" *Id*. (quoting

4   claim 22 (partial) and claim 38 (partial) (emphasis added)). Oracle also points to claim 15, which

5   "refers to clinical terms being 'enterprise terms corresponding to a company and *domain* terms

6   corresponding to a *predetermined study.*'" *Id*. at 10-11 (quoting claim 15) (emphasis in Oracle's

7   brief)). Oracle argues that "[b]ecause the patentee differentiated clinical studies from 'particular'

8   clinical studies elsewhere in the patent, importing this limitation into Claim 1 would be improper."

9   *Id*. (citing *Phillips*, 415 F.3d at 1315).

10   Fourth, Oracle argues that DrugLogic's proposed construction is incorrect because it would

11   eliminate the distinction between external, company and domain terms, and would render

12   synonymous "clinical terms" and "domain terms." *Id*. at 11. In doing so, it would conflict with the

13   specification by reading out a preferred embodiment and would render claims redundant, a result

14   that should be avoided. *Id*. at 11.

15   DrugLogic argues that while its proposed construction admittedly excludes a preferred

16   embodiment, it is proper in light of the prosecution history under the doctrine of prosecution

17   disclaimer, for the same reasons discussed above in connection with the term "clinical terms."

18   DrugLogic Responsive Brief ('221 patent) at 19-20. Because of the applicant's disavowal of claim

19   scope, DrogLogic argues, the words "clinical terms" in this claim term include only "domain terms"

20   (which are undisputedly specific to a particular study) and company terms that arise out of or relate

21   to a particular clinical study. *Id*. at 18 & n. 13. DrugLogic argues that Oracle's reliance on the

22   doctrine of claim differentiation fails because the presumption of claim differentiation is rebuttable

23   and the presumption is rebutted here on the basis of the narrowing amendments made during patent

24   prosecution. *Id*. at 19-20. DrugLogic further asserts that Oracle's proposed construction would

25   render the claims invalid. *Id*. at 20.

26   In its reply brief, Oracle notes that DrugLogic does not address in its responsive brief

27   Oracle's assertion that this claim term would be understandable to a lay person and therefore

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1 requires no construction. Oracle Reply Brief ('221 patent) at 10. Oracle further counters that

2 DrugLogic's reliance on the specification's use of the term "particular" in connection with its

3 description of domain terms does not warrant importing this limitation into the construction of this

4 claim term. Oracle Reply Brief ('221 patent) at 11. Finally, Oracle argues that DrugLogic's

5 reliance on the doctrine of prosecution disclaimer fails for the reasons discussed above. *Id*. at 11.

6   **b.   Analysis**

7   DrugLogic's proposed construction of this claim term is based on its contention that the

8 applicant narrowed the scope of the '221 claims to exclude clinical terms obtained from medical

9 dictionaries and thesauruses. As discussed above, the Court finds that DrugLogic's reliance on the

10 doctrine of prosecution disclaimer is misplaced on this question. Because the applicant did not

11 clearly disavow embodiments in which clinical terms are drawn from medical dictionaries and

12 thesauruses, the construction proposed by DrugLogic is inconsistent with the specification. In

13 particular, the specification explains that the invention can be implemented using three types of

14 clinical terms – those drawn from medical dictionaries and thesauruses, company terms and domain

15 terms. *See* '221 patent, col. 7, ll. 9-18. It further explains that clinical terms from a *particular study*

16 are "domain terms." *Id*. DrugLogic's proposed construction also fails under the doctrine of claim

17 differentiation to the extent that certain dependent claims limit the scope of the claims to domain

18 terms limited to particular studies. *See, e.g.,* Claims 15, 38. Therefore, the Court adopts Oracle's

19 proposed construction of the term "defining a plurality of clinical terms for use in conjunction with a

20 clinical study," that is, "choosing a plurality of terms pertaining to the study or observation of

21 medical patients for use in conjunction with a clinical study."

22   **3.   Verbatim Clinical Data (Claim 12)**

Oracle's Proposed Construction	DrugLogic's Proposed Construction
No construction required or "raw information related to the study or observation of medical patients"	"exact word-for-word raw clinical data from a clinical study"

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1   **a.   Parties' Positions**

2   According to Oracle, the parties disagree as to this claim term on two questions: 1) whether

3   "verbatim" means "raw" (Oracle), or "exact word-for-word raw" (DrugLogic); and 2) whether

4   "clinical data" means "information related to the study or observation of medical patients" (Oracle)

5   or "clinical data from a clinical study" (DrugLogic). Oracle's Opening Brief ('221 patent) at 12.

6   As to the first question, Oracle contends that its proposed construction is correct because

7   "throughout the specification, the patent refers to verbatim data as 'raw' data." *Id*. (citing '221

8   Abstract ("A study term extracted from raw clinical data is presented to determine a corresponding

9   match in the thesaurus of clinical terms"); col. 2, ll. 8-11 ("The system and method classify the terms

10 derived from raw clinical data to effect a consistent clinical term classification throughout the

11 clinical study")).[13]   Because the parties agree, according to Oracle, that "clinical data" means "at

12 minimum, 'pertaining to the study or observation of medical patients,' . . .Oracle's proposed

13 construction of 'verbatim clinical data' as 'raw information related to the study or observation of

14 medical patients' merely combines these agreed-upon elements and explains that 'data' is

15 'information.'" *Id*. at 12-13. Oracle asserts that DrugLogic's proposed construction of "verbatim" as

16 "exact word-for-word raw" is confusing because it includes three possible meanings for "verbatim"

17 – exact, word-for-word, and raw. *Id*. at 13. Further, Oracle contends, this definition "may imply

18 that the entirety of the raw clinical data needs to be scanned." *Id*.

19   As to the second question, Oracle argues that DrugLogic's definition of "clinical data" as

20 "clinical data from a clinical study" is improper because it includes the claim term in the definition

21 of the claim term, which is not appropriate in claim construction. *Id*. (citing *Volterra Semiconductor*

22 *Corp. v. Primarion, Inc.*, 2009 WL 6357679, at * 11 (N.D. Cal. Nov. 17, 2009)). Oracle asserts that

23 DrugLogic is attempting to "tack a limitation onto the claim that does not exist in the claim language

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26   [13]Oracle notes in a footnote, citing Cobert's Manual of Drug Safety and Pharmacovigilance, that
    verbatim terms are generally "terms used by reporters, patients and investigators" rather than terms from
27 a medical dictionary. *Id*. at 12 n. 4; Baker Decl., Ex. B at 80. It also notes that the parties have agreed
    that the term "verbatim study terms" means "exact words included in raw clinical data."

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1   itself . . .by suggesting that the only verbatim data relevant here are those derived from clinical

2   studies." *Id*. Oracle contends that such a construction would exclude "data collected from, *e.g.*,

3   doctors observing patients in their day-to-day clinical practices, pharmacists reporting customer

4   feedback, and patient-initiated reports of adverse effects." *Id*. According to Oracle, "[n]othing in

5   the language of the patent suggests an intent to exclude such information." *Id*.

6   DrugLogic defends its proposed construction of "verbatim data" as "exact word-for-word

7   raw clinical data" rather than merely "raw clinical data,"arguing that Oracle's proposed construction

8   "essentially removes the word 'verbatim' from the construction of 'verbatim clinical data' in claim

9   12." DrugLogic Responsive Brief ('221 patent) at 20. Because a claim construction should give

10   meaning to all the terms of the claim, DrugLogic contends, Oracle's proposed construction should

11   be rejected. *Id*. at 20-21. Further, DrugLogic asserts, the plain meaning of the word "verbatim" is

12   "exact word-for-word." *Id*. at 21 & Ex. 12 (definition from dictionary.com, defining "verbatim" as

13   "In exactly the same words; word-for-word"), Ex. 13. (definition from Webster's on-line dictionary

14   defining "verbatim" as "in the exact words, word-for-word"). DrugLogic also offers the following

15   excerpt from the specification in support of its proposed construction:

16   The verbatim study terms 26 are provided from clinical data 38 by any suitable method,
            including the scanner 34 from hardcopy data reports, the PC 36 from a data entry or other
17   suitable application, or a public access network such as the Internet 38 via an HTML browser
            or other format. **The raw, unprocessed clinical data** 38 is then interrogated for verbatim
18   study terms 26 to provide to the input device 14 for classification. In a particular
            embodiment, the **raw, unprocessed clinical data** 38 is received by a clinical study data
19   management application.

20   *Id*. (quoting '221 patent, col. 3, ll. 51-62) (emphasis added by DrugLogic). According to

21   DrugLogic, this passage supports its proposed construction because the word "unprocessed" refers

22   to the fact that the "verbatim data" is in its "unchanged, original form." *Id*. Similarly, DrugLogic

23   asserts, the prosecution history supports DrugLogic's proposed construction because the applicants

24   referred to "deriving clinical terms . . . from free text as originally captured." *Id*. & Ex. 9 (excerpt of

25   prosecution history) at 7.

26   DrugLogic argues that its construction of "clinical data" as "clinical data from a clinical

27   study" is consistent with the specification, the language of claim 12 and the prosecution history. *Id*.

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at 21-22. DrugLogic points to the following statements in the specification in support of its position: "the same clinical term may appear in a variety of formats throughout the clinical data produced by the study" ('221 patent, col. 1, ll. 42-43); "In a typical study, verbatim study terms 26 are extracted from raw clinical data by a variety of methods . . ." ('221 patent, col. 3, ll. 34-35); and "In a particular embodiment, the raw, unprocessed clinical data 38 is received by a clinical study data management application . . ." ('221 patent, col. 3, ll. 58-60). DrugLogic further contends that a plain reading of claim 12 as a whole "leaves no doubt that the verbatim clinical data must come from a clinical study." *Id*. at 22. Finally, DrugLogic cites the following passage in the prosecution history in support of its position:

> By way of background, a clinical study is typically a research process by which clinical data is gathered, such that it assists a user in answering scientific questions and determining whether certain methods of prevention, diagnosis, and treatment are safe or effective. Ideally in this process, the clinical data is gathered, captured, classified and organized. One of the most time-consuming tasks within the clinical trial process is classifying and organizing the clinical data.

Id. (quoting Ex. 9 at 7-8).

Oracle argues in its reply brief that DrugLogic has implicitly conceded that the '221 patent uses the terms "raw" and "verbatim" interchangeably and yet offers no explanation for the inclusion of "further verbiage" in its proposed construction. Oracle Reply Brief ('221 patent) at 12. Further, Oracle argues, DrugLogic has made "no attempt to address Oracle's reasoned argument" that DrugLogic's proposed construction confusingly suggests that all of the raw data must be scanned. *Id*. Oracle also asserts that DrugLogic has failed to address its argument that it is improper to limit "clinical data" to that which is obtained from clinical studies. *Id*.

b.   Analysis

The primary disputes the Court must resolve with respect to the claim term "verbatim clinical data" are: 1) whether the term requires construction; 2) how "verbatim" should be construed; and 3) whether "clinical data" must be obtained from clinical studies or rather may be obtained from other types of reports as well . While it is not clear that there is any significant dispute regarding the meaning of "verbatim," the parties' positions as to the meaning of the words "clinical data" reflect a

1   more fundamental disagreement that must be decided by the Court as a matter of law. Therefore, the

2   Court finds that it is necessary to construe this claim term.

3   As to the word "verbatim," Oracle criticizes DrugLogic's proposed construction on the basis

4   that it is based, in part, on extrinsic evidence. It does not, however, dispute that the word, as used in

5   the '221 patent, carries its ordinary and customary meaning, that is, "in exactly the same words" or

6   "word-for-word." The Court agrees with DrugLogic that Oracle's proposed construction does not

7   adequately capture this meaning: while it makes clear that the data is drawn from raw data, it does

8   not reflect the fact that this data is not changed or processed in any way, but rather, is scanned word-

9   for-word. In the specification, the applicant conveyed this meaning by describing the data as "raw,

10 *unprocessed* clinical data." See, e.g., '221 patent, col. 3, ll. 58-60. During prosecution, the concept

11 was conveyed by describing the verbatim clinical data as "free text *as originally captured*."

12 DrugLogic Responsive Brief ('221 patent), Ex. 9 (excerpt of prosecution history) at 7. Therefore,

13 the Court includes in its construction language that conveys that the clinical data is taken word-for-

14 word from the raw data. The possibility of confusion relating to whether an entire piece of data must

15 be scanned – cited by Oracle in support of its opposition to DrugLogic's proposed construction –

16 does not appear to the Court to be significant, as nothing in DrugLogic's proposed construction

17 states such a requirement. Nonetheless, given that DrugLogic does not appear to dispute Oracle's

18 contention that an *excerpt* of raw data falls within the scope of the claim, this concern can be

19 addressed by inserting additional language making clear that an excerpt is sufficient.

20   As to the words, "clinical data," the Court concludes that these words refer to information

21 from clinical studies. The plain meaning of these words, as well as at least two passages in the

22 specification, support this conclusion. *See* '221 patent, col. 1, ll. 23-31 ("[C]linical studies are often

23 undertaken during preparation of a new consumer product. . . . a large quantity of clinical data is

24 generated by such studies"), col. 3, 34-35 ("In a typical study, verbatim study terms 26 are extracted

25 from raw clinical data . . . "). Further, the language of claim 12 supports the conclusion that

26 "clinical data" comes from clinical studies, reciting "scanning verbatim clinical data" and "parsing

27

28

1 verbatim *study terms* from the clinical data."   Because the parties have already stipulated to the

2 meaning of "clinical studies,"[14] the Court need not further construe the words "clinical data."

3   Based on the foregoing, the Court construes "verbatim clinical data" as "raw, word-for word

4 information, whether in its entirety or in excerpted form, from a clinical study."

5 **V.   CONCLUSION**

6   For the reasons discussed above, the Court adopts the following constructions:

Claim Term	Court's Construction
"allowing analytical drill down"	"allowing a user to redo the analysis in real time at different levels of the hierarchy"
"hyperlinks . . . corresponding to places in an up and down hierarchy"	"such links . . . corresponding to different levels of a structured medical dictionary, such as MedDRA"
"associating respective hyperlinks with a plurality of portions of such data and analysis"	"creating a plurality of links within web pages for some of the previously stored information and some of the results of the statistical analysis such that clicking on the information or results causes a user to jump to another place in the same web page or to an entirely different web page"
"permitting the at least one remote user to analyze safety issues"	"permitting the at least one remote user to run a statistical analysis that finds 'signals' such as anomalies in a random population, changes against a known background, or coherent targets in a noise background"
"permitting at least one remote user to access such data through the World Wide Web"	"permitting a user at one computer to access information reflecting occurrences of adverse events on a different computer or server, through one or more Internet servers"
"a comparator to measure the reactions to the at least one [drug/substance] of interest against a user-defined backdrop" "comparator"	"an application that compares the reactions to a particular drug of two user-defined data sets"

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26   [14]"Clinical studies" is construed by the parties to mean "a research process by which clinical
27 data is gathered in order to answer scientific questions and determine whether certain methods of
   prevention, diagnosis, and treatment are safe or effective." Joint Claim Construction and Prehearing
28 Statement [Docket No. 102] at 4.

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"a correlator to look for correlated signal characteristics among drug, reaction, and demographic information" "correlator"	"an analysis tool that concurrently searches drug, reaction and demographic information to measure the degree of association among pairs of certain drug, reaction, and demographic values"
"clinical terms"	"terms pertaining to the study or observation of medical patients, such as terms in a medical dictionary"
"defining a plurality of clinical terms for use in conjunction with a clinical study"	"choosing a plurality of terms pertaining to the study or observation of medical patients for use in conjunction with a clinical study"
"verbatim clinical data"	"raw, word-for word information, whether in its entirety or in excerpted form, from a clinical study"

The Court will hold a further case management conference on September 21, 2012 at 1:30 p.m. On or before September 14, 2012, the parties shall file a joint case management conference statement containing a proposed schedule for the remainder of the case.

IT IS SO ORDERED.

Dated: August 21, 2012

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JOSEPH C. SPERO
United States Magistrate Judge